

AP/1761\$

**TRANSMITTAL LETTER  
(General - Patent Pending)**

Docket No.  
112703-213

JPW

Re Application Of: McGrew, G., et al.

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/024,669	December 14, 2001	Corbin, Arthur L.	29156	1761	2933

Title: **CHEWING GUMS AND RELATED PRODUCTS THAT PROVIDE BREATH FRESHENING CHARACTERISTICS**

TO THE DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE:

Transmitted herewith is:

Transmittal of Appeal Brief (duplicate); Appellants' Appeal Brief (12 pgs. in triplicate); including: Claims Appendix (6 pgs.); Evidence Appendix (1 pgs.); Exhibit A-D; Summary Appendix (3 pages); and Check in the amount of \$500.00.

in the above identified application.

- ☐ No additional fee is required.
- ☒ A check in the amount of \$500.00 is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. 02-1818 as described below.
- ☐ Charge the amount of
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Dated: January 16, 2005

Signature

Robert M. Barrett  
Reg. No. 30,142

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January 16, 2005

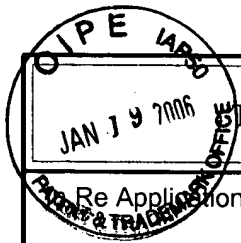
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Signature of Person Mailing Correspondence

Heather Foster

Typed or Printed Name of Person Mailing Correspondence

CC:



## TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No.  
112703-213

Re Application Of: McGrew, G., et al.

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/024,669	December 14, 2001	Corbin, Arthur L.	29156	1761	2933

Invention: CHEWING GUMS AND RELATED PRODUCTS THAT PROVIDE BREATH FRESHENING CHARACTERISTICS

COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on

The fee for filing this Appeal Brief is: \$500.00

- ☒ A check in the amount of the fee is enclosed.
- ☐ The Director has already been authorized to charge fees in this application to a Deposit Account.
- ☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 02-1818
- ☐ Payment by credit card. Form PTO-2038 is attached.

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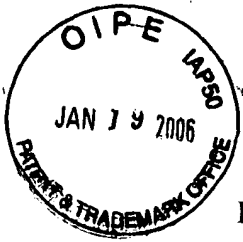
(Date)

Signature of Person Mailing Correspondence

Heather Foster

Typed or Printed Name of Person Mailing Correspondence

cc:



THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant(s): McGrew, G., et al.  
Appl. No.: 10/024,669  
Conf. No.: 2933  
Filed: December 14, 2001  
Title: CHEWING GUMS AND RELATED PRODUCTS THAT PROVIDE BREATH  
FRESHENING CHARACTERISTICS  
Art Unit: 1761  
Examiner: Corbin, Arthur L.  
Docket No.: 112703-213

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPEAL BRIEF**

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on November 16, 2005. This Appeal is taken from the Final Rejection dated August 19, 2005.

**I. REAL PARTY IN INTEREST**

The real party in interest for the above-identified patent application on appeal is Wm. Wrigley Jr. Company by virtue of an Assignment dated February 8, 2002 and February 11, 2002 and recorded at the United States Patent and Trademark Office at reel 012658, frame 0554.

**II. RELATED APPEALS AND INTERFERENCES**

Appellants, Appellants' legal representative and the Assignee of the above-identified patent application are not currently aware of any application, patent, appeal or interference or any other prior and pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

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### **III. STATUS OF CLAIMS**

Claims 1-12, 15-20, 28-35 and 37-49 are pending in the above-identified patent application. Claims 1-12, 15-20, 28-35 and 37-49 are being appealed in this Brief. A copy of the appealed claims is provided in the Claims Appendix.

### **IV. STATUS OF AMENDMENTS**

A Final Office Action was mailed on August 19, 2005. Appellants filed a Response to the Final Office Action on October 18, 2005. An Advisory Action was mailed on October 28, 2005. In the Advisory Action, the Response was considered but was deemed not to place the patent application in condition for allowance. A copy of the Final Office Action is attached as Exhibit A in the Evidence Appendix and a copy of the Advisory Action is attached as Exhibit B in the Evidence Appendix.

### **V. SUMMARY OF CLAIMED SUBJECT MATTER**

A summary of the invention by way of reference to the drawings and specification for each of the independent claims (Claims 1, 12, 28, 34 and 40) may be found in Summary Appendix attached to this Brief.

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations below, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1-5, 7-12, 15-18, 20, 28-30, 32-35 and 37-39 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,380,530 to Hill (“*Hill*”).

A copy of *Hill* is attached as Exhibit C in the Evidence Appendix.

2. Claims 6, 19, 31 and 40-49 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Hill* in view of U.S. Patent No. 6,030,605 to D’Amelia, et al. (“*D’Amelia*”).

A copy of *D’Amelia* is attached as Exhibit D in the Evidence Appendix.

## VII. ARGUMENT

### A. LEGAL STANDARDS

#### 1. Anticipation under 35 U.S.C. §102

Anticipation is a factual determination that “...requires the presence in a single prior art disclosure of each and every element of a claimed invention.” *Lewmar Marine, Inc. v. Barient, Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Moreover, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)(*emphasis added*).

Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. *See, e.g. Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364 (Fed. Cir. 2002). In this regard, a reference disclosing “substantially the same thing” is not enough to anticipate. *Jamesbury Corp. v. Litton Indust. Prod., Inc.*, 756 F.2d 1556, 1560 (Fed. Cir. 1985). A reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found.

Further, anticipation cannot be shown by combining more than one reference to show the elements of the claimed invention. *In re Saunders*, 444 F.2d 599 (C.C.P.A. 1971). All elements of a claimed invention must be disclosed in one, solitary reference. As such, it is clear that a

reference cannot be utilized to render a claimed invention anticipated without identical disclosure.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). Inherency may not be established by probabilities or possibilities. *In re Robertson*, 169 F.3d 743, 745 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

2. Obviousness under 35 U.S.C. §103

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Whether a claim is obvious is a question of law that is based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *In re Zurko*, 59 U.S.P.Q.2d 1693, 1696 (Fed. Cir. 2001).

The Patent Office has the initial burden of proving a *prima facie* case of obviousness and this burden remains until final decision. *Stratoflex, Inc. v. Aeroquip Corp.*, 218 U.S.P.Q. 871 (Fed. Cir. 1983). In making this determination, the question is not whether the differences between the prior art and the claims themselves would have been obvious, but whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1616 (Fed. Cir. 1999). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so, found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

The Federal Circuit has held that “obvious to try” is not the standard under 35 U.S.C. §103. *In re Roemer*, 59 U.S.P.Q.2d 1527, 1531 (Fed. Cir. 2001). “An obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claim result would be obtained if certain directions were pursued.” *In re Eli Lilly and Co.*, 14 U.S.P.Q. 2d 1741, 1743 (Fed. Cir. 1990). Also, one cannot use “hindsight reconstruction to pick and choose among isolated disclosures in the prior art” to re-create the claimed invention. *In re Fine*, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988). Thus, the mere fact that the prior art can be combined to achieve Appellants’ claimed invention is not enough to demonstrate obviousness. *In re Laskowski*, 10 U.S.P.Q. 2d 1397 (Fed. Cir. 1989). Rather, the prior art, in its entirety, must provide the teaching to make the combination obvious. *In re Dance*, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998).

Of course, “a prior art reference is relevant for all that it teaches to those of ordinary skill in the art.” *In re Fritch*, 23 U.S.P.Q.2d 1780, 1782 (Fed. Cir. 1992). In this regard, “a prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the appellant.” *In re Haruna*, 58 U.S.P.Q.2d 1517, 1522 (Fed. Cir. 2001). “If the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the appellant is entitled to grant of the patent.” *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Further, it is improper to use an invention as a template for its own reconstruction based on hindsight knowledge of the patented invention when the prior art does not contain or suggest that knowledge. *Sensonics, Inc. v. Aerosonic Corp.*, 38 U.S.P.Q.2d 1551, 1554 (Fed. Cir. 1996). In this regard, the invention “must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made.” *Id.* As such, the Federal Circuit has acknowledged the need for “rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.” *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

B. THE INDEPENDENT CLAIMS

Independent Claim 1 is directed to a chewing gum. The chewing gum includes a coated gum center. The gum center and coating both include a metal salt that is designed to provide breath freshening characteristics to a consumer of the chewing gum.

Independent Claim 12 is directed to a chewing gum product. The chewing gum product includes a metal salt that is designed to provide breath freshening characteristics. The chewing gum product also includes a gum center including a water-soluble portion and a water-insoluble portion. The gum center includes the metal salt. The chewing gum product further includes a coating surrounding the gum center, including a cooling agent and a metal salt.

Independent Claim 28 is directed to a product containing a metal salt designed to provide breath freshening properties. The product includes a gum center and a coating surrounding the gum center. The gum center includes a metal salt selected from the group consisting of zinc and copper salts. The gum center also includes a water-soluble portion and a water-insoluble portion. The coating includes a cooling agent and a metal salt selected from the group consisting of zinc and copper salts.

Independent Claim 34 is directed to a method for treating halitosis. The method comprises the step of chewing a chewing gum comprising a coated gum center. The coated gum center includes a water-soluble portion and a water-insoluble portion. The coating at least substantially surrounds the gum center. The coating and gum center are prepared with a metal salt ingredient designed to provide breath freshening characteristics. The combined amount is a therapeutically effective amount.

Independent Claim 40 is directed to a chewing gum product. The chewing gum product includes a gum center including a water-soluble portion and a water-insoluble portion. The chewing gum product also includes a coating including a copper salt.

C. THE REJECTIONS

In the Final Office Action, Claims 1-5, 7-12, 15-18, 20, 28-30, 32-35 and 37-39 were rejected under 35 U.S.C. §102(b) as stated in Section VI above. Specifically, the claims were rejected as being anticipated by *Hill*. The Patent Office has maintained that the cited reference discloses or teaches all of the elements of the claimed invention and, more specifically, teaches a

coated gum center, wherein the gum center and coating both include a metal salt that is designed to provide breath freshening characteristics to a consumer of the chewing gum.

Additionally, Claims 6, 19, 31 and 40-49 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Hill* in view of *D'Amelia*. The Patent Office has maintained that it would have been obvious to one of ordinary skill at the time of the invention to substitute a copper salt as claimed by Appellant for the zinc salt used in *Hill*.

D. THE REJECTION OF CLAIMS 1-5, 7-12, 15-18, 20, 28-30, 32-35 AND 37-39 SHOULD BE REVERSED BECAUSE THE PATENT OFFICE HAS FAILED TO ESTABLISH ANTICIPATION

Appellants respectfully disagree with and traverse the rejection of Claims 1-5, 7-12, 15-18, 20, 28-30, 32-35 and 37-39 because the cited references fail to disclose all elements of the claimed invention.

As discussed above, in order for a reference to anticipate a claim, the reference must comprise every single element of a claimed invention. Appellants respectfully submit that *Hill* fails to disclose, teach or suggest every element of the claimed invention. In particular, *Hill* fails to disclose, teach or suggest the use of a metal salt in a gum center of a coated chewing gum.

*Hill* is directed to a chewing gum that is coated by an emulsion coating having a therapeutic agent such as stannous fluoride. See, *Hill*, Abstract. To this end, *Hill* teaches including active ingredients in its gum coatings, but not the gum center. See, *Hill*, column 15, lines 20-22. *Hill* includes a therapeutic agent in the coating because of the fast release rates for introducing the agent into the oral cavity. See, *Hill*, column 16, lines 22-27. Accordingly, *Hill* provides that:

[t]he therapeutic chewing gums of the present invention are characterized by an emulsion coating as described earlier, wherein the emulsion coating contains one or more therapeutic substances. At the outset of chewing the coated gum, the coating-therapeutic substance(s) mixture is released from the surface of the chewing gum into the oral cavity at a controlled rate and in a predetermined amount....

The relatively fast rate of release from the coated chewing gum of the emulsion coating-microbially active stannous fluoride mixture into the oral cavity would be an effective means for introducing

controlled and efficacious levels of the microbially active stannous ion into the oral cavity. *Hill*, column 15, lines 12-30.

Therefore, *Hill* fails to disclose, teach or suggest the use of a metal salt in a gum center of a coated chewing gum.

The Patent Office has maintained that each element of the claimed invention is anticipated by *Hill*. In particular, the Patent Office relies on a statement in *Hill* referring to what is disclosed in U.S. Pat. Nos. 4,950,479 and 5,057,309 to Hill et al. in an attempt to distinguish the invention in *Hill* from these patents. The specification states at column 8, lines 38-44:

Hill et al., U.S. Pat. Nos. 4,950,479 and 5,057,309 disclose the claimed emulsions of the present invention in "liquid center chewing gums". However, there is no teaching or suggestion that the Hill et al. emulsions can be coated onto chewing gum and subsequently released into the oral cavity at a predetermined plaque disrupting level and rate.

The Patent Office extrapolates from this reference that *Hill* discloses that its emulsions can be included in liquid center chewing gums. See Office Action dated August 19, 2005, pages 2-3, and the Advisory Action dated October 28, 2005. Appellants respectfully submit, however, that *Hill* does not disclose that the emulsions in *Hill* can be included in liquid center chewing gums. As provided above, *Hill* simply states that "U.S. Pat. Nos. 4,950,479 and 5,057,309 disclose the claimed emulsions of the present invention in 'liquid center chewing gums'". *Hill* does not indicate which of the emulsions claimed in *Hill* are disclosed in liquid center chewing gums in U.S. Patent Nos. 4,950,479 and 5,057,309. Indeed, not all of the "claimed emulsions" in *Hill* include a metal salt. Furthermore, *Hill* fails to disclose or suggest anywhere that the disclosed emulsion coatings having active ingredients can be present in liquid center chewing gums.

Although the Patent Office attempts to rely on *Hill*'s reference to U.S. Patent Nos. 4,950,479 and 5,057,309 to suggest that *Hill* discloses a gum center including a metal salt, it does not reject any of the claims over these patents, nor does the Patent Office provide any support to show that the patents referred to in *Hill* disclose emulsions having a metal salt used in a liquid center gum. This is not surprising, however, since neither U.S. Patent No. 4,950,479 nor U.S. Patent No. 5,057,309 disclose emulsions containing a metal salt in a chewing gum center – even liquid center chewing gums, especially a metal salt designed to treat halitosis or provide

breath freshening characteristics or properties as in the claimed invention. Therefore, because the Patent Office cannot rely on *Hill*'s reference to U.S. Patent Nos. 4,950,479 and 5,057,309 to suggest that *Hill* discloses a gum center including a metal salt, *Hill* fails to anticipate the claimed invention.

Not only does *Hill* not disclose a metal salt in a gum center of a coated chewing gum, *Hill* teaches away from the use of active ingredients, such as metal salts, in the gum center or gum base. Acknowledging the difficulty of releasing active ingredients from a gum base, *Hill* further states:

[T]he release of active ingredients from the gum base is a major problem and one which has confronted the industry for a long time despite the fact that slab chewing gums on a weight basis are more than 75% water soluble materials such as sugars, sugar substitutes, corn syrup, and the like.

It therefore has been the usual practice in the industry when manufacturing chewing gums having active ingredients to deposit the active ingredient upon the exterior of a gum nugget or center, usually with an underlying thin layer of hard sugar. The outer layer of hard sugar is generally produced by tumbling the units in coating pans into which saturated solutions of sugar are poured and the water driven out by aeration, the finished piece being commonly called "candy coated gum." The use of candy coated gum allows for the dissolution of the active ingredient in the mouth before it is chewed into the gum base. (emphasis added.) *Hill*, column 8 line 63 through column 9, line 16.

This is consistent with the objective of *Hill* to prepare a chewing gum composition for treating conditions which require a "relatively fast rate of release from the coated chewing gum" as stated above. *Hill*, column 4, lines 44-46, and Table II. Therefore, *Hill* teaches away from the use of active ingredients, such as metal salts, in the gum center or gum base as in the claimed invention.

*Hill* also fails to disclose, teach or suggest the use of metal salts in providing breath freshening characteristics or a method of treating halitosis. Instead, the invention of *Hill* is directed to plaque disruption, gingivitis control, hypersensitivity treatment, stomatitis treatment (canker sores) and microbes. *Hill*, column 9, lines 19-24, and column 23, lines 54-59. In a further attempt to support its rejection of the claims, the Patent Office states in the Advisory Action dated October 28, 2005, that "the metal salts in *Hill* inherently provide breath freshening

since they control gingivitis, plaque and microbes, all of which contribute to bad breath”. Appellants respectfully submit, however, that just because *Hill* treats gingivitis, plaque and microbes, *Hill* does not inherently disclose providing breath freshening.

Incorporating a zinc compound in the coating in *Hill* does not necessarily provide breath freshening as suggested by the Patent Office. As stated above, the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. Appellants’ Specification at, for example, pages 1 and 2, explains that the problem with delivering metal salts, such as zinc and copper salts, to the oral cavity to treat bad breath is the speed with which the vehicle and the metal salts are washed away. To this end, each of independent Claims 1, 12, 28, and 34 of the claimed invention, include metal salt in a gum center to treat halitosis or to provide breath freshening characteristics or properties. This teaching is in complete contrast to the teaching in *Hill* where active ingredients are associated only with the coating to facilitate the “relatively fast rate of release from the coated chewing gum” required to treat conditions other than bad breath. *Hill*, column 16, lines 22-24. Therefore, incorporating a zinc compound in the coating in *Hill* does not necessarily provide breath freshening as suggested by the Patent Office. Thus, Appellants respectfully submit that *Hill* does not inherently disclose providing breath freshening.

Therefore, *Hill* fails to disclose each element of the claimed invention, even inherently. Accordingly, *Hill* does not anticipate the claimed invention, and the rejection of Claims 1-5, 7-12, 15-18, 20, 28-30, 32-35 and 37-39 should be reversed.

E. THE REJECTION OF CLAIMS 6, 19, 31 AND 40-49 SHOULD BE REVERSED BECAUSE THE PATENT OFFICE HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS

Claims 6, 19, 31 and 40 to 49 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Hill* in view of *D’Amelia*. The Patent Office has stated that it would have been obvious to substitute a copper salt, as in Claims 6, 19, 31 and 40-49, for the zinc salt used in *Hill*. To support its conclusion, the Patent Office has relied on *D’Amelia* to demonstrate that “both copper and zinc salts are used alternatively as breath freshening additives in chewing gum”. See Office Action dated April 14, 2005. Appellants respectfully disagree with and traverse the rejection of Claims 6, 19, 31 and 40-49 because the cited references alone, or in combination, do

not disclose, teach or suggest the elements of the claimed invention and because one of ordinary skill in the art, at the time the claimed invention was made, would not have been motivated to combine the references. In fact, *Hill* teaches away from the combination with *D'Amelia*. As such, the cited references do not render the claimed invention obvious.

*Hill* alone, or in combination with *D'Amelia*, fails to disclose or suggest the use of copper salts in a chewing gum coating. *D'Amelia* does not disclose, teach or suggest a coated chewing gum. It follows then that *D'Amelia* fails to disclose the use of a copper salt in the coating of a chewing gum. *D'Amelia* only discloses breath freshening composition coated carriers in solid oral carriers, such as lozenges and tablets, which are distinguished from and discussed separately from chewing gum. *D'Amelia*, column 4, lines 4-7 and column 5, lines 16-43. Therefore, there is nothing in *D'Amelia* to suggest that copper salts could be used in a chewing gum coating. Therefore, the combination of *Hill* with *D'Amelia* fails to teach or suggest the use of copper salts in a chewing gum coating.

Furthermore, one skilled in the art would not be motivated to modify *Hill* or combine *Hill* with *D'Amelia* to arrive at the claimed invention. As discussed above, *Hill* is directed to using a zinc compound in emulsion coatings only. *Hill* provides no motivation for including an active ingredient in a gum center as in *D'Amelia*. *D'Amelia*, on the other hand, fails to suggest a coated chewing gum as in *Hill* in which a copper salt could be incorporated. As stated above, the test for obviousness is not whether the prior art could be modified or combined to achieve the claimed invention, but rather whether the art suggests the modification. Appellants respectfully submit that, because *Hill* is directed to chewing gum coatings and *D'Amelia* does not even suggest a chewing gum coating, it would not have been obvious to one of skill in the art to use *D'Amelia* to modify *Hill*.

In addition, *Hill* teaches away from the combination with *D'Amelia*. In complete contrast to the teachings of *D'Amelia* directed to the use of copper salts in the gum center only, *Hill* teaches to avoid introducing active ingredients in the gum base because it is well known in the art that the release of active ingredients from the gum base is incomplete and slow and constitutes a problem to be solved. *Hill*, column 8, lines 63-65. Appellants respectfully submit that a person of ordinary skill in the art would not be motivated to use a reference that is directed to including the active ingredient in the gum base, as in *D'Amelia*, to modify *Hill* when *Hill*

clearly teaches away from exactly what *D'Amelia* teaches. Therefore, because *Hill* provides no motivation for including active ingredients in the gum center, as in *D'Amelia*, and because *Hill* even teaches away from such, one of ordinary skill in the art would not have been motivated to consult *D'Amelia* to modify *Hill*.

Accordingly, in an attempt to re-create what the claimed invention discloses, the Patent Office has applied improper hindsight to selectively piece together teachings of *Hill* with the teachings of *D'Amelia* in the absence of motivation from the references or the art to make such a combination. Without the requisite motivation to combine these teachings, it is clearly improper as being "hindsight reconstructive" to simply state that a copper salt used in a gum base in *D'Amelia* can substitute for the zinc salt used in a coating in *Hill*. Therefore, without the requisite motivation to combine the references or to modify *Hill* with *D'Amelia*, the Patent Office has failed to establish a *prima facie* case of obviousness. Accordingly, Appellants respectfully submit that the rejection of Claims 6, 19, 31 and 40-49 should be reversed.

Moreover, Claims 6, 19 and 31 depend from Claims 1, 12, and 28, respectively, which, for the reasons discussed above, are in condition for allowance. Therefore, Appellants respectfully submit that, for at least this reason, Claims 6, 19 and 31 are also in condition for allowance.

### VIII. CONCLUSION

Appellants respectfully submit that Claims 1-5, 7-12, 15-18, 20, 28-30, 32-35 and 37-39 are not anticipated by the cited references under 35 U.S.C. §102(b). Appellants further respectfully submit that Claims 6, 19, 31 and 40-49 are non-obvious in view of the cited references under 35 U.S.C. §103. Accordingly, Appellants respectfully submit that the rejection of pending Claims 1-12, 15-20, 28-35 and 37-49 is erroneous in law and in fact and should be reversed by the Board.

Respectfully submitted,

BELL BOYD & LLOYD LLC

BY \_\_\_\_\_

Robert M. Barrett  
Reg. No. 30,142  
Customer No.: 29156

Dated: January 16, 2006

**CLAIMS APPENDIX**  
**PENDING CLAIMS ON APPEAL OF**  
**U.S. PATENT APPLICATION SERIAL NO. 10/024,669**

1. A chewing gum comprising:  
a coated gum center, wherein the gum center and coating both include a metal salt that is designed to provide breath freshening characteristics to a consumer of the chewing gum.
2. The chewing gum of Claim 1 wherein the coating includes a surfactant.
3. The chewing gum of Claim 2 wherein the surfactant is a non-ionic surfactant selected from the group consisting of poly (C<sub>2</sub>-C<sub>4</sub>-alkoxy) esters of C<sub>18</sub>-C<sub>20</sub> fatty acids, C<sub>4</sub>-C<sub>20</sub> alkyl poly (C<sub>2</sub>-C<sub>4</sub>-alkoxy) esters of C<sub>8</sub>-C<sub>20</sub> fatty acids, poly (C<sub>2</sub>-C<sub>4</sub> alkoxy) esters of sorbitan, poly (C<sub>2</sub>-C<sub>4</sub> alkoxy)ated) – C<sub>1</sub>-C<sub>20</sub> alcohols, polyethylene glycols, and mixtures thereof.
4. The chewing gum of Claim 1 wherein the metal salt is chosen from the group consisting of food acceptable zinc and copper salts.
5. The chewing gum of Claim 1 wherein the metal salt includes a zinc salt selected from the group consisting of: zinc stearate; zinc acetate; zinc gluconate; zinc lactate; zinc ammonium sulfate; zinc chromate; zinc citrate; zinc dithionate; zinc fluorosilicate; zinc tartrate; zinc formate; zinc iodide; zinc nitrate; zinc phenol sulfonate; zinc salicylate; zinc sulfate; zinc succinate; zinc glycerophosphate; and zinc halides.
6. The chewing gum of Claim 1 wherein the metal salt includes a copper salt selected from the group consisting of: copper stearate; copper acetate; copper gluconate; copper lactate; copper ammonium sulfate; copper chromate; copper citrate; copper dithionate; copper fluorosilicate; copper tartrate; copper formate; copper iodide; copper nitrate; copper phenol sulfonate; copper salicylate; copper sulfate; copper succinate; copper glycerophosphate; and copper halides.

7. The chewing gum of Claim 2 wherein the coating includes an edible oil.
8. The chewing gum of Claim 1 wherein the coating includes a cooling agent.
9. The chewing gum of Claim 8 wherein the cooling agent is selected from the group consisting of: menthol; monomenthyl succinate and salts thereof; cyclic carboxamides; acyclic carboxamides; menthyl acetate; menthyl lactate; menthone ketals; 3-menthoxypropane-1,2 diol; and mixtures thereof.
10. The chewing gum of Claim 1 including at least one beneficial component selected from the group consisting of: fluoride salts; calcium salts; pyrophosphates; polyphosphates; antibacterial agents; cetylpyridinium chloride; chlorhexidine; essential oil mixtures containing menthol, eucalyptol, methyl salicylate, and thymol; botanical extracts; tooth desensitizing agents; potassium nitrate; plaque surface adhesion inhibitors; polydimethylsiloxane/surfactant; abrasive agents; silicas; surfactants; sodium laurel sulfate; and antibiotics.
11. The chewing gum of Claim 7 wherein the edible oil is a vegetable oil.
12. A chewing gum product comprising:
  - a metal salt that is designed to provide breath freshening characteristics;
  - a gum center including a water-soluble portion, a water-insoluble portion, wherein the gum center includes the metal salt; and
  - a coating surrounding the gum center, including a cooling agent and a metal salt.
15. The chewing gum of Claim 12 wherein the coating includes a surfactant.
16. The chewing gum of Claim 15 wherein the surfactant is a non-ionic surfactant selected from the group consisting of poly (C<sub>2</sub>-C<sub>4</sub>-alkoxy) esters of C<sub>18</sub>-C<sub>20</sub> fatty acids, C<sub>4</sub>-C<sub>20</sub> alkyl poly (C<sub>2</sub>-C<sub>4</sub>-alkoxy) esters of C<sub>8</sub>-C<sub>20</sub> fatty acids, poly (C<sub>2</sub>-C<sub>4</sub> alkoxy) esters of sorbitan, poly (C<sub>2</sub>-C<sub>4</sub> alkoxy)ated) – C<sub>1</sub>-C<sub>20</sub> alcohols, polyethylene glycols, and mixtures thereof.

17. The chewing gum of Claim 12 wherein the metal salt is chosen from the group consisting of zinc and copper.

18. The chewing gum of Claim 12 wherein the metal salt includes a zinc salt selected from the group consisting of: zinc stearate; zinc acetate; zinc gluconate; zinc lactate; zinc ammonium sulfate; zinc chromate; zinc citrate; zinc dithionate; zinc fluorosilicate; zinc tartrate; zinc formate; zinc iodide; zinc nitrate; zinc phenol sulfonate; zinc salicylate; zinc sulfate; zinc succinate; zinc glycerophosphate; and zinc halides.

19. The chewing gum of Claim 12 wherein the metal salt includes a copper salt selected from the group consisting of: copper stearate; copper acetate; copper gluconate; copper lactate; copper ammonium sulfate; copper chromate; copper citrate; copper dithionate; copper fluorosilicate; copper tartrate; copper formate; copper iodide; copper nitrate; copper phenol sulfonate; copper salicylate; copper sulfate; copper succinate; copper glycerophosphate; and copper halides.

20. The chewing gum of Claim 12 wherein the coating includes an edible oil.

28. A product containing a metal salt designed to provide breath freshening properties, comprising:

a gum center including a metal salt selected from the group consisting of zinc and copper salts, a water-soluble portion, a water-insoluble portion; and

a coating surrounding the gum center, including a cooling agent and a metal salt selected from the group consisting of zinc and copper salts.

29. The chewing gum of Claim 28 wherein the coating includes an edible oil.

30. The chewing gum of Claim 28 wherein the metal salt includes a zinc salt selected from the group consisting of: zinc stearate; zinc acetate; zinc gluconate; zinc lactate; zinc ammonium sulfate; zinc chromate; zinc citrate; zinc dithionate; zinc fluorosilicate; zinc tartrate; zinc formate; zinc iodide; zinc nitrate; zinc phenol sulfonate; zinc salicylate; zinc sulfate; zinc succinate; zinc glycerophosphate; and zinc halides.

31. The chewing gum of Claim 28 wherein the metal salt includes a copper salt selected from the group consisting of: copper stearate; copper acetate; copper gluconate; copper lactate; copper ammonium sulfate; copper chromate; copper citrate; copper dithionate; copper fluorosilicate; copper tartrate; copper formate; copper iodide; copper nitrate; copper phenol sulfonate; copper salicylate; copper sulfate; copper succinate; copper glycerophosphate; and copper halides.

32. The chewing gum of Claim 28 wherein the cooling agent is selected from the group consisting of: menthol; monomenthyl succinate and salts thereof; cyclic carboxamides; acyclic carboxamides; menthyl acetate; menthyl lactate; menthone ketals; 3-menthoxypropane-1,2 diol; and mixtures thereof.

33. The chewing gum of Claim 28 including at least one beneficial component selected from the group consisting of: fluoride salts; calcium salts; pyrophosphates; polyphosphates; antibacterial agents; cetylpyridinium chloride; chlorhexidine; essential oil mixtures containing menthol, eucalyptol, methyl salicylate, and thymol; botanical extracts; tooth desensitizing agents; potassium nitrate; plaque surface adhesion inhibitors; polydimethylsiloxane/surfactant; abrasive agents; silicas; surfactants; sodium laurel sulfate; and antibiotics.

34. A method for treating halitosis comprising the steps of chewing a chewing gum comprising a coated gum center including a water-soluble portion, a water-insoluble portion, wherein the coating at least substantially surrounds the gum center, the coating and gum center being prepared with a metal salt ingredient designed to provide breath freshening characteristics, the combined amount being a therapeutically effective amount.

35. The method of treating halitosis of Claim 34, wherein the gum further includes in the coating surrounding the gum center, a cooling agent.

37. The method of Claim 35 wherein the gum center and coating each include the metal salt.

38. The chewing gum product of Claim 28 wherein the coating includes a surfactant.

39. The chewing gum product of Claim 38 wherein the surfactant is a non-ionic surfactant selected from the group consisting of poly (C<sub>2</sub>-C<sub>4</sub>-alkoxy) esters of C<sub>18</sub>-C<sub>20</sub> fatty acids, C<sub>4</sub>-C<sub>20</sub> alkyl poly (C<sub>2</sub>-C<sub>4</sub>-alkoxy) esters of C<sub>8</sub>-C<sub>20</sub> fatty acids, poly (C<sub>2</sub>-C<sub>4</sub> alkoxy) esters of sorbitan, poly (C<sub>2</sub>-C<sub>4</sub> alkoxylated) – C<sub>1</sub>-C<sub>20</sub> alcohols, polyethylene glycols, and mixtures thereof.

40. A chewing gum product comprising:  
a gum center including a water-soluble portion and a water-insoluble portion; and  
a coating including a copper salt.

41. The chewing gum of Claim 40 wherein the gum center and the coating each include the copper salt.

42. The chewing gum product of Claim 40 wherein the copper salt is selected from the group consisting of: copper stearate; copper acetate; copper gluconate; copper lactate; copper ammonium sulfate; copper chromate; copper citrate; copper dithionate; copper fluorosilicate; copper tartrate; copper formate; copper iodide; copper nitrate; copper phenol sulfonate; copper salicylate; copper sulfate; copper succinate; copper glycerophosphate; and copper halides.

43. The chewing gum product of Claim 40 wherein the coating includes an edible oil.

44. The chewing gum product of Claim 40 wherein the coating includes a cooling agent.

45. The chewing gum of Claim 44 wherein the cooling agent is selected from the group consisting of: menthol; monomenthyl succinate and salts thereof; cyclic carboxamides; acyclic carboxamides; menthyl acetate; menthyl lactate; menthone ketals; 3-menthoxypropane-1,2 diol; and mixtures thereof.

46. The chewing gum product of Claim 40 wherein the gum center includes a zinc salt selected from the group consisting of: zinc stearate; zinc acetate; zinc gluconate; zinc lactate; zinc ammonium sulfate; zinc chromate; zinc citrate; zinc dithionate; zinc fluorosilicate; zinc tartrate; zinc formate; zinc iodide; zinc nitrate; zinc phenol sulfonate; zinc salicylate; zinc sulfate; zinc succinate; zinc glycerophosphate; and zinc halides.

47. The chewing gum product of Claim 40 including at least one beneficial component selected from the group consisting of: fluoride salts; calcium salts; pyrophosphates; polyphosphates; antibacterial agents; cetylpyridinium chloride; chlorhexidine; essential oil mixtures containing menthol, eucalyptol, methyl salicylate, and thymol; botanical extracts; tooth desensitizing agents; potassium nitrate; plaque surface adhesion inhibitors; polydimethylsiloxane / surfactant; abrasive agents; silicas; surfactants; sodium laurel sulfate; and antibiotics.

48. The chewing gum product of Claim 40 wherein the coating includes a surfactant.

49. The chewing gum product of Claim 48 wherein the surfactant is a non-ionic surfactant selected from the group consisting of poly (C<sub>2</sub>-C<sub>4</sub>-alkoxy) esters of C<sub>18</sub>-C<sub>20</sub> fatty acids, C<sub>4</sub>-C<sub>20</sub> alkyl poly (C<sub>2</sub>-C<sub>4</sub>-alkoxy) esters of C<sub>8</sub>-C<sub>20</sub> fatty acids, poly (C<sub>2</sub>-C<sub>4</sub> alkoxy) esters of sorbitan, poly (C<sub>2</sub>-C<sub>4</sub> alkoxylated) – C<sub>1</sub>-C<sub>20</sub> alcohols, polyethylene glycols, and mixtures thereof.

## **EVIDENCE APPENDIX**

EXHIBIT A: Final Office Action mailed on August 19, 2005.

EXHIBIT B: Advisory Action mailed on October 28, 2005.

EXHIBIT C: U.S. Patent No. 5,380,530 to Hill ("*Hill*") cited by the Patent Office in the Office Actions mailed on February 23, 2004, September 16, 2004, and April 14, 2005, and the Final Office Action mailed on August 19, 2005.

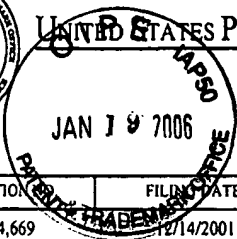
EXHIBIT D: U.S. Patent No. 6,030,605 to D'Amelia, et al. ("*D'Amelia*") cited by the Patent Office in the Office Actions mailed on February 23, 2004, September 16, 2004, and April 14, 2005, and the Final Office Action mailed on August 19, 2005.

**EXHIBIT A**

**Final Office Action mailed on August 19, 2005**



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,669	12/14/2001	Gordon N. McGrew	112703-213	2933

29156 7590 08/19/2005

BELL, BOYD & LLOYD LLC  
P. O. BOX 1135  
CHICAGO, IL 60690-1135

EXAMINER

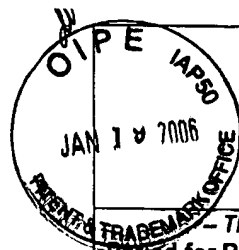
CORBIN, ARTHUR L

ART UNIT PAPER NUMBER

1761

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



## Office Action Summary

Application No.

10/024,669

Applicant(s)

MCGREW ET AL.

Examiner

Arthur L. Corbin

Art Unit

1761

**The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15-20, 28-35 and 37-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-20, 28-35, 37-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 7-12, 15-18, 20, 28-30, 32-35 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill (columns 8, 10, 12, 13, 15-17 and 20).

Applicant is referred to paragraph No. 4, Paper No. 041105.

4. Claims 6, 19, 31 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill in view of D'Amelia et al.

Applicant is referred to paragraph No. 5, Paper No. 041105.

5. Applicant's arguments filed July 18, 2005 have been fully considered but they are not persuasive. Applicant's contention, that Hill teaches away from using active ingredients, such as metal salts, in gum centers, is without merit. What Hill actually discloses in column 8, lines 63-68 is that the release of active ingredients from a gum base is a problem. However, Hill does not mention liquid centers in chewing gums in referring to this problem. In fact, Hill goes so far as to state that the "emulsions of the

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present invention" can be included in "liquid center chewing gums" (column 8, lines 38-40).

The metal salts in Hill inherently provide breath-freshening characteristics since they control gingivitis and plaque and are the same metal salts used by applicant.

D'Amelia et al not only discloses the use of breath freshening metal salts in lozenges and tablets, as applicant recognizes, but also in chewing gum as well (column 1, lines 35-43). Thus, D'Amelia et al is clearly analogous to and properly combinable with Hill.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

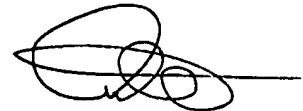
7. Any inquiry concerning this communication from the examiner should be directed to Arthur L. Corbin whose telephone number is (571) 272-1399. The examiner can generally be reached on Monday--Friday from 10:30 to 8:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. Corbin/dh  
August 17, 2005



ARTHUR L. CORBIN  
PRIMARY EXAMINER

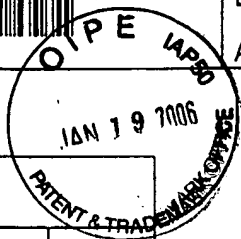
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**Arthur L. Corbin**

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Class	Subclass	Date	Examiner

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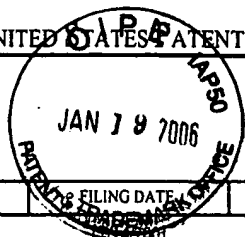
**EXHIBIT B**

**Advisory Action mailed on October 28, 2005**



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,669	10/28/2005	Gordon N. McGrew	112703-213	2933
29156 7590 10/28/2005				
BELL, BOYD & LLOYD LLC				
P. O. BOX 1135				
CHICAGO, IL 60690-1135				
EXAMINER				
CORBIN, ARTHUR L				
ART UNIT		PAPER NUMBER		
1761				

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/024,669

Applicant(s)

MCGREW ET AL.

Examiner

Arthur L. Corbin

Art Unit

1761

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s) \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

Arthur L. Corbin  
Primary Examiner  
Art Unit: 1761

Continuation of 11. does NOT place the application in condition for allowance because: Hill discloses that the emulsions "of the present invention", i.e. in Hill, can be included in liquid center chewing gums (col. 8, lines 38-40 of Hill). The metal salts in Hill inherently provide breath freshening since they control gingivitis, plaque and microbes, all of which contribute to bad breath, and are the same metal salts used by applicant. .

**EXHIBIT C**

**U.S. Patent No. 5,380,530 to Hill**



US005380530A

**United States Patent** [19]**Hill**[11] **Patent Number:** **5,380,530**[45] **Date of Patent:** **Jan. 10, 1995**[54] **ORAL CARE COMPOSITION COATED GUM**[75] **Inventor:** **Ira D. Hill, Locust, N.J.**[73] **Assignee:** **WhiteHill Oral Technologies, Hazlet, N.J.**[21] **Appl. No.:** **996,939**[22] **Filed:** **Dec. 29, 1992**[51] **Int. Cl.<sup>6</sup>** ..... **A61K 9/68; A23G 3/30**[52] **U.S. Cl.** ..... **424/440; 424/48; 424/439; 514/900; 514/902; 514/975**[58] **Field of Search** ..... **424/440, 48, 439, 441**[56] **References Cited****U.S. PATENT DOCUMENTS**

2,806,814	9/1957	Richter	167/93
4,609,543	9/1986	Morris et al.	424/440

**OTHER PUBLICATIONS**L. Menaker, *The Biologic Basis of Dental Caries*, Chapter 5, Harper & Row (1980).L. Menaker, *The Biologic Basis of Dental Caries*, Chapter 11, Harper & Row (1980).L. Menaker, *The Biologic Basis of Dental Caries*, Chapter 12, Harper & Row (1980).L. Menaker, *The Biological Basis of Dental Caries*, Chapter 14, Harper & Row (1980).L. Menaker, *The Biologic Basis of Dental Caries*, Chapter 16, Harper & Row (1980).L. Menaker, *The Biologic Basis of Dental Caries*, Chapter 18, Harper & Row (1980).Topitsoglou et al., *Caries Res.*, 17:369-378 (1983).Segal et al., *Journal of Pharmaceutical Sciences*, vol. 74, No. 1, (1985).Loesche et al., *JADA*, vol. 108, 597 (1984).Makinen et al., *JADA*, vol. 111, 745, (1985).Southard et al., *JADA*, vol. 108, 338 (1984).Mordenti et al., *Journal of Pharmaceutical Sciences*, vol. 71, No. 12 (1982).Fine et al., *Journal of Clinical Periodontology*, 12: 660-666 (1985).Plaque, *Current Approaches to Prevention and Control*, *JADA*, vol. 109, Nov. 1984.Winter et al., *Caries Res.*, 16:349-352 (1982).*Primary Examiner*—G. S. Kishore*Assistant Examiner*—James M. Spear*Attorney, Agent, or Firm*—Ernest V. Linek

[57]

**ABSTRACT**

Disclosed are several oral hygiene preparations including plaque disrupting and gingivitis control preparations in the form of chewing gums, wherein a chewing gum is coated with a plaque disrupting emulsion containing an ingestible surfactant and a polydimethyl siloxane emulsified therein, and wherein the emulsion coating can further contain a therapeutic substance such as the gingivitis control substance stannous fluoride.

**17 Claims, No Drawings**

## ORAL CARE COMPOSITION COATED GUM

## BACKGROUND OF THE INVENTION

The present invention relates to oral hygiene and specifically to the frequent interference with the formation of plaque and/or the control of gingivitis, hypersensitivity, etc., by regularly chewing a specially coated chewing gum. Plaque is a microbial coating on tooth surfaces, bound together by natural polymers, (mucopolysaccharides,) formed by microbial action on the cell debris, food remnants, sugars and starches in the mouth. Embedded in this polymer matrix are the bacteria normal to the oral cavity but, when trapped against tooth surfaces and protected by the matrix from easy removal, are in excellent position for "mischief." Most dental texts implicate plaque in the formation of caries, or tooth decay. In addition, these embedded bacteria release toxins that cause gingivitis, bleeding and swelling of the gums. Gingivitis can lead to periodontitis in which gums recede, pockets of infection form and teeth loosen.

Plaque formation is an ongoing process. Various gel and paste dentifrice preparations, mouth rinses, mouth prerinses and spray preparations make plaque and/or tartar control claims. One disadvantage of these toothpaste and rinse preparations is that only a relatively short time during which the teeth are being cleaned or the mouth is being rinsed is available for these preparations to take effect. These preparations generally have little residual effect on plaque formation. Additionally, some of these preparations such as mouth rinses and prerinses contain various antimicrobial substances which may alter the critically balanced microflora of the mouth. Another disadvantage of these toothpaste and rinse preparations is the general infrequency of use. That is, most are used once or perhaps twice daily and seldom when they are most needed, e.g., after meals, snacks, smoking, drinking, coffee breaks, etc. The present invention also relates to therapeutic oral hygiene preparations including preparations suitable for the control of gingivitis.

Effective oral hygiene requires that three control elements be maintained by the individual:

1. Physical removal of stains, plaque and tartar. This is accomplished in the strongest sense by scraping and abrasion in the dentist's office. Self administered procedures are required frequently between visits and range from tooth brushing with an appropriate abrasive toothpaste through flossing and water jet action down to certain abrasive foods and even the action of the tongue against tooth surfaces.
2. Surfactant Cleansing. This is required to remove food debris and staining substances before they adhere to the tooth surfaces as well as normal dead cellular (epithelial) material which is continually sloughed off from the surfaces of the oral cavity and microbial degradation products derived from all of

the above. The ease of surfactant cleansing is enhanced if the surface of the tooth has a lower surface energy so that debris and plaque precursors cannot firmly adhere. Besides the obvious hygienic and health benefits related to simple cleanliness provided by surfactants, there is an important cosmetic and sense-of-well-being benefit provided by surfactant cleansing. Research has shown that the primary source of bad

breath is the retention and subsequent degradation of dead cellular material sloughed off continuously by the normal, health mouth.

3. Frequency of Cleansing. This is perhaps the most difficult to provide in today's fast-paced work and social environment. Most people recognize that their teeth should be brushed at least 3 times a day plus after each snacking occasion.

The simple fact is that most of the population brush once a day, some brush morning and evening, but precious few carry toothbrush and dentifrice to use the other three or four times a day for optimal oral hygiene.

Consumer research suggests that the population brushes an average of 1.3 times a day. Thus, the 24 hour period between brushings for a majority of the population provides optimum plaque forming conditions with no interruptions.

Since plaque is regarded by most of the dental profession as a causative agent leading to various dental pathologies as noted above, there is considerable desire by most consumers to remove or prevent the formation of plaque on a daily basis. There are three oral care strategies which address the problem of plaque: abrasion, anti-microbial agents and removal of precursors to plaque.

1. Abrasive removal of the plaque film, once it has firmly adhered to the tooth surface, is the only totally effective cleansing mechanism. Again, professional dental hygiene is the most effective, but recently a number of special abrasive toothpastes have been accepted by dental organizations as partially removing adhered plaque and the tartar which subsequently forms from the plaque;

2. Antimicrobial action could affect plaque formation in two ways, (a) reducing the number of bacteria in the mouth which form the mucopolysaccharides and (b) killing those bacteria trapped in the film to prevent further growth and metabolism. However, the medical and dental community is divided about the advisability of frequent use of antimicrobial agents in the mouth in rinses or prerinses, especially the most effective ones, except under strict supervision of licensed practitioners. There are a number of reasons given, but one concern is that such materials would upset the ecological balance of the mouth. A balanced, "friendly" microbial population is necessary to prevent pathogenic organisms from taking over, and

3. Removal of plaque precursors requires the reduction of food sources and the building blocks required for the bacteria to synthesize the mucopolysaccharides which polymerize into plaque film. Going far back into the chain of events leading to plaque formation and interrupting the chain has much to commend it as a sound oral hygiene strategy. However, for this strategy to be effective, the plaque building blocks must be interrupted periodically. As noted above, hereto, the oral hygiene preparations described above fall short on "frequency-of-use" basis.

For reference, see, L. Menaker, *The Biologic Basis of Dental Caries*, Chapters 5, 11, 12, 14, 16 and 18, Harper & Row (1980).

Efforts have been made over the years to address the problem of dissolution or demineralization of tooth enamel and the resultant formation of dental caries. As is well known, dental plaque accumulates on the teeth as the result of the growth and metabolism of certain bacteria, such as *Streptococcus mutans*, which are nour-

ished by cariogenic comestibles, particularly those containing sugars. Such bacteria are involved in the formation of dental plaque which accumulates as a deposit on the surfaces of teeth. The metabolism of bacteria within the plaque results in the generation of high levels of acids which are detrimental to the teeth and contribute to the production of dental caries.

Stannous fluoride,  $\text{SnF}_2$ , has been used in dentistry since the 1950's as a chemical adjunct to prevent dental caries. Topical applications of  $\text{SnF}_2$  consistently have shown dramatic reductions in dental caries activity with minimal side effect. Evidence has also accumulated that  $\text{SnF}_2$  has antibacterial properties which may affect its anticaries properties as well as inhibit plaque formation and gingivitis. See Tinanoff, "Review of the Antimicrobial Action of Stannous Fluoride," 1990.

Addy et al., 1988, reported a desensitizing effect for fresh  $\text{SnF}_2$  due to a covering or obturation of tubules in hypersensitive dentine. There is also an indication that  $\text{SnF}_2$  may be effective in controlling *Candida* sp. colonization of denture plaque. See Hill et al., U.S. Pat. Nos. 5,057,310; 5,098,711 and 5,165,913.

Prescription ( $R_x$ ) nonaqueous gels of glycerine and  $\text{SnF}_2$ , such as Scherer Laboratory's, Gel-Kam are perhaps the most widely used form of  $R_x$   $\text{SnF}_2$  available commercially. These gels are generally prescribed for the treatment of caries and hypersensitive teeth as well as gingivitis.

Unfortunately, in spite of its promising results, the effective use of  $\text{SnF}_2$  has been drastically limited by its inherent instability in the presence of oxygen, water, abrasives, and the like.

In addition to the inherent instability of  $\text{SnF}_2$ , most  $\text{SnF}_2$  products suffer from poor patient compliance, attributed in part to the nonaqueous carriers required to maintain activity, to the metallic taste of the product, as well as to the methods of application which usually include a brushing step separate and apart from the use of a dentifrice. For example, brush-on  $\text{SnF}_2$  gels require the patient to brush at least four times/day, i.e., twice with the gel and twice with a regular dentifrice. Compliance in such a treatment regimen drops to about 30%, an unacceptable level, as documented by Has-trieter's review of Wolf et al.'s 1989 Gel-Kam study.

With the advent of fluoride in water and fluoridated dentifrices, gum disease, gingivitis, hypersensitive teeth, root caries in the elderly and *Candida* sp. disorders in denture wearers, have replaced caries in children as the dominant oral care concerns of the '90's requiring special treatment. For example, a recent NIH survey established that 90% of adults age 65 or older have some form of gum disease, and over 123 million adults in the U.S. suffer from gum disease. Moreover, one out of six adults suffer from hypersensitivity at one time or another, while ten million adults are chronic sufferers. Additionally, the millions of adults who undergo periodontal treatment, or have their teeth cleaned, can experience hypersensitivity discomfort ranging from an uncomfortable feeling to severe pain. Most denture wearers suffer from "denture breath" attributed in part to *Candida* sp. colonization of denture plaque and/or plaque-like coatings on dentures.

Recent reviews on dentine hypersensitivity have deduced that the transmission of pain stimuli across dentine is by a hydrodynamic mechanism. This is confirmed by the open tubules (microscopic openings) present in normal teeth). Various stimuli cause fluid move-

ment in these tubules which activate nerve endings in the pulp.

Considerable evidence has accumulated in the past 20 years to show that topical applications of  $\text{SnF}_2$  reduce *S. mutans* levels as well as demonstrate antiplaque properties. These antiplaque and antigingivitis benefits of  $\text{SnF}_2$  appear to be related to frequent, i.e., several times/day treatment with  $\text{SnF}_2$ .

Root caries is attributed to the recession of gums and is a common condition in the elderly. *Candida* sp. yeast disorders are estimated to occur in approximately 90% of denture wearers. These disorders lead to, or are associated with, stomatitis and thrush (candidiasis).

There is therefore a definite need in the art for oral hygiene preparations containing microbially active  $\text{SnF}_2$  that retain the desired antibacterial activity over the use life of the preparations. There is also a need in the art for oral hygiene preparations containing microbially active  $\text{SnF}_2$  that are pleasant to use, encourage compliance and support frequent usage throughout the day. There is a further need in the art for new methods of treating caries, coronal caries, gingivitis, plaque buildup, hypersensitivity and *Candida* sp. infections of denture plaque with microbially active  $\text{SnF}_2$  products in various forms.

There is a further need in the art for delivery vehicles for microbially active  $\text{SnF}_2$  which achieve rapid transport of  $\text{SnF}_2$  into fissures, crevices in dentures and other prosthesis where the microbial activity of  $\text{SnF}_2$  can be employed to fight plaque and disrupt the colonization of denture plaque by yeast type organisms while protecting the  $\text{SnF}_2$  from degradation of its microbial activity.

In view of the foregoing it is an object of this invention to provide an oral hygiene preparation that disrupts plaque formation with or without providing various therapeutic substances to the oral cavity such as  $\text{SnF}_2$  for treating caries, gingivitis, hypersensitivity and *Candida* sp. infections.

It is also an object of this invention to provide an oral hygiene preparation containing various therapeutic substances including microbially active  $\text{SnF}_2$  that are pleasant to use, encourages compliance and repetitive usage.

It is a further object of this invention to provide an effective method for treating caries, gingivitis, hypersensitivity, plaque buildup and *Candida* sp. infections.

It is yet another object of this invention to provide a method of manufacturing oral hygiene preparations for fighting plaque as well as preparations containing a microbially active form of  $\text{SnF}_2$ .

Chewing gum has over the years been advocated as a possible excellent adjunct for cleaning the teeth because people find the chewing of gum very pleasurable and chew gum more frequently for much longer periods of time than they brush their teeth. Chewing gum is especially advantageous for use in circumstances where tooth brushing is not possible or convenient, such as after lunch, while traveling, or while working.

Chewing gum stimulates saliva because of the chewing action, flavors and sweetness. In the first few minutes of chewing, studies have shown a ten-fold increase in salivary flow. After the flavor and sweeteners are extracted, there is still a three-fold increase in saliva flow. This saliva stimulation after eating has a number of benefits. For example, stimulating saliva after eating helps:

dilute and clear food debris and fermentable carbohydrates from the mouth,

deliver buffers such as bicarbonate, proteins, urea, to the plaque,  
neutralize plaque acid due to buffering action and dilution,  
inhibit mineral loss due to shorter time of acid exposure, and  
promote enamel, remineralization due to higher pH and the enamel protective effects of calcium, phosphate and fluoride.

Most eating occasions lead to prolonged acid production. Dentists advise snacking in moderation, brushing teeth twice daily with a fluoride toothpaste, and cleaning teeth soon after eating. However, since tooth brushing with toothpaste after eating is often impractical and inconvenient, the use of a salivary stimulant can reduce acid production and facilitate a returning to a near neutral pH conducive to remineralization. Two recent papers by Dr. S. L. Creanor, et al., in Glasgow and Drs. R. H. Manning and W. M. Edgar in Liverpool on remineralization illustrates the importance of stimulating saliva after eating in a fluoride environment, e.g., Caries Res. (26:3.92 No. 22, Page 215 and J. Clin. Dent., Vol. III No. 3, respectively.

As is well known, salivation is an important physiological function which has several benefits in addition to those relating to digestion.

One of those benefits is the washing of tooth enamel surfaces and their surrounding soft tissues or game. This washing provides a preventive effect against disease in direct relation to the rate of salivary flow from the four major salivary glands which empty into the human mouth under various stimulations.

Chewing gum not only provides the flavor and chewing factors for saliva stimulation but also achieves mechanical dental cleansing, making it an ideal and natural mechanism for promoting dental health.

The use of chewing gums to deliver various substances into the oral cavity is extensively described by the prior art. Generally, these references teach incorporating various substances into the gum mix during the processing of the gum. The substances incorporated in the gum base are then released from the gum during masticating. For example;

A. Some prior art methods have been disclosed for the incorporation of active or insoluble ingredients into sugar containing gum bases, U.S. Pat. No. 3,075,884 teaches a method for obtaining the release of solid active ingredients from a gum base by dispersing the solid active ingredient throughout the corn syrup ingredient of the gum prior to the admixture of the corn syrup with the gum base; U.S. Pat. No. 3,011,919 teaches a method for incorporating active ingredients, including phosphates, into slab chewing gum, by coating the active ingredients with wet sugar;

B. U.S. Pat. No. 3,352,689 does disclose the formulation of a sugarless gum prepared from gum base, gum acacia-in-water, gum acacia powder, sorbitol, mannitol, sweeteners and flavoring agents, which may contain additional active ingredients such as phosphates; however, no statement is made concerning the form in which these active ingredients must be or the manner for incorporating these active ingredients into the sugarless gum formulation so as to insure the release of effective amounts of the active ingredients into the oral cavity. See also U.S. Pat. No. 3,655,866;

C. It is also well known in the art that mineral adjuncts such as calcium carbonate are added to chewing gum compositions to act as fillers or to provide non-stick properties. Thus, for example, U.S. Pat. No. 4,357,355, to E. Koch et al., discloses a non-stick bubble gum base composition that contains about 5% to about 25% by weight of calcium carbonate;

D. A number of chewing gum compositions have been disclosed in the art which are said to inhibit or reduce plaque in the oral cavity. For example, U.S. Pat. Nos. 4,148,872, 4,150,112, 4,156,715, 4,156,716, 4,157,385, 4,159,315, 4,160,054, 4,160,820, 4,161,517, and 4,170,632, all to A. Wagenknecht et al., disclose chewing gum compositions effective in inhibiting or reducing plaque in the oral cavity. These chewing gum compositions contain a chewing gum base and a surface active agent, and, in some instances, a zinc compound or a plaque inhibiting flavor. In addition, a calcium carbonate abrasive may be included in the aforementioned chewing gum compositions. See also, U.S. Pat. Nos. 3,974,293, 3,984,574; 3,651,206; 4,568,537; 4,474,749 and 4,828,820. U.S. Pat. No. 4,029,760 discloses pharmaceutical chewing gums for the treatment of gingivitis containing at least one carra-geenin;

E. U.S. Pat. No. 4,400,372, to J. C. Muller et al., discloses a chewing gum composition containing a chewing gum base, at least one non-toxic source of an acid and calcined kaolin particles having a median diameter of 2 micrometers or less, wherein substantially all of the kaolin particles are less than 20 micrometers in diameter;

F. U.S. Pat. No. 3,590,120, to J. C. Muller, discloses a chewing gum composition containing an insoluble gum base; zirconium silicate particles as a cleaning and polishing agent, wherein at least 20% by weight of said particles are up to about 3 microns in size and between 5% and 40% by weight are about 10 to about 20 microns in size; and a dental plaque removing agent which may be sodium carbonate, sodium bicarbonate, or chloroform. See also U.S. Pat. Nos. 3,255,018 and 3,651,206; and

G. The use of cationic antimicrobial agents to reduce plaque and gingivitis has been recognized for many years wherein these antimicrobial compositions are included in the chewing gum base. Included among references disclosing, such compositions are U.S. Pat. Nos. 3,937,805, Feb. 10, 1976 to Harrison; 3,937,807, Feb. 10, 1976 to Haefele; 4,080,441, Mar. 21, 1978 to Gaffar et al.; 4,241,049, Dec. 23, 1980 to Colodney et al.; 3,925,543, Dec. 9, 1975 to Donohue; 4,256,731, Mar. 17, 1981 to Curtis et al.; 4,217,342, Aug. 12, 1980 to Gaffar; 4,259,316, Mar. 31, 1981 to Nakashima et al.; 4,039,409, Jan. 4, 1982 to CollPalagos et al.; and U.S. Pat. No. 4,169,885, Oct. 2, 1979 to Raaf et al.

The "Effect of Chewing Gums Containing Xylitol, Sorbitol or a Mixture of Xylitol and Sorbitol on Plaque Formation, Ph Changes and Acid Production in Human Dental Plaque": is published in Carles Res., 17: 369-378 (1983).

Historically, researchers in gum have focused on incorporating various substances from flavors to plaque fighting substances into the gum base, or gum base adjuncts for controlled released during chewing. For example:

- A. Yolles, in U.S. Pat. No. 3,818,107 issued Jun. 18, 1974, describes chewing gums which incorporate the flavor in a polymeric backbone. Yolles states that the flavor release in the chewing gum is sustained by the molecular arrangement of the flavor group. In U.S. Pat. No. 3,651,206 issued to Litchfield et al., on Mar. 21, 1972, are described chewing gums containing various aliphatic aldehydes as anticaries agents. Various oral preparations for preventing dental plaque are described in U.S. Pat. No. 3,940,476 issued Feb. 24, 1976 to Hass. Comollo states in U.S. Pat. No. 3,984,574 issued Oct. 5, 1976 that non-tacky chewing gums may be made containing mono- and diglycerides of fatty acids in an amount up to ten percent (10%) by weight of the base composition;
- B. Clark, in U.S. Pat. No. 3,930,026 issued Dec. 30, 1975, describes the enhancement of flavor in chewing gums obtained by sorbing the flavoring onto a hydrophilic colloid in conjunction with a surfactant. Among the surfactants disclosed are anionic materials, including sodium di(2-ethylhexyl)sulfosuccinate. Clark also states that nonionic surfactants may be used to sorb the flavor into the gum including fatty acid monoglycerides or fatty acid diglycerides; British Pat. No. 1,296,952 reported by Cancro et al. and published Nov. 22, 1972 states that plaque and calculus may be diminished by zinc phenolsulphonate and certain enzymes in dentifrice compositions. The Cancro patent also describes the use of certain abrasives, buffering agents, and various surfactants. British Pat. No. 1,372,932 published Nov. 6, 1974, describes purported anticaries compositions including chewing gums, dentifrices and candy-like products. In particular, the aforementioned British patent states that stearyl-2-lactylate has been found effective to inhibit the production of dextran in the mouth;
- C. U.S. Pat. No. 3,821,417 issued to Westall et al. on Jun. 28, 1974, describes the use of dihydrochalcone in chewing gums. This patent further describes the use of butylated hydroxyanisole, butylated hydroxytoluene and propyl gallate as antioxidants in chewing gums. Durross, in U.S. Pat. No. 3,973,041 issued Aug. 3, 1976 describes the use of sorbitol powder, butylated hydroxyanisole, and glycerine in chewing gums. Additional disclosures of sorbitol as well as other sugars, such as xylitol, are made in various United States Patents including: U.S. Pat. No. 4,000,320 issued to Klose et al., on Dec. 28, 1976; U.S. Pat. No. 3,899,593 issued to Hammond et al., on Aug. 12, 1975; U.S. Pat. No. 3,914,434 issued Oct. 21, 1975 to Bohni; U.S. Pat. No. 3,296,079 issued Jan. 3, 1967 to Griffin; and U.S. Pat. No. 3,655,866 issued Apr. 11, 1972 to Billoti; and
- D. Various additives for chewing gums have been suggested to reduce or eliminate the problem of chewing gum adhering to dentures and artificial teeth, such as lecithin as disclosed in U.S. Pat. No. 2,197,719, lanolin as disclosed in U.S. Pat. No. 2,197,718 and silicone oils as disclosed in U.S. Pat. No. 2,761,782. U.S. Pat. No. 3,255,018 to Comollo discloses the use of water-soluble hydrolyzable tannin, such as tannic acid or polymer-tannic acid edicts, in combination with type A or B gelatin water-containing hydrophilic polymer gels. See

also U.S. Pat. Nos. 2,273,425; 2,383,145; 2,429,664; 3,285,450; 3,440,060 and 3,984,574.

The general disclosure of nonionic surfactants for use in oral products is also well discussed in the prior art, particularly with reference to dentifrices and rinses. For example:

A. Tomlinson in U.S. Pat. No. 4,130,636 discloses dental creams and mouthwash compositions free from bitter surfactant taste wherein the surfactant is an alkyl polyglycol ether carboxylate. A mouthwash having superior taste characteristics and improved clarity is disclosed by Januszewski in U.S. Pat. No. 3,639,563. The improved clarity is obtained by selecting nonionic surface active agents for their ability to solubilize one or more oily components contained in the mouthwash. Thus, polyoxypropylene-polyoxyethylene block polymers and polyoxyethylene derivatives of sorbitan esters are disclosed as useful surfactants which solubilize certain oily components and thus provide improved clarity in the mouthwash; Pensak et al., in U.S. Pat. No. 3,947,570, also disclose a visually clear, haze-free mouthwash free from unpleasant taste which includes a nonionic surfactant which is a polyoxyethylene derivative of a sorbitan ester;

B. Jackson et al., in U.S. Pat. No. 2,677,700, disclose polyoxyalkylene surface-active block polymers, Example 6 thereof disclosing a propoxylated cetyl alcohol. There is an indication, in Column 24, that the surface active agents disclosed would have freedom from the usual bitter taste generally associated with nonionic surfactants of the prior art, and

C. Schmolka, U.S. Pat. No. 4,465,661 discloses various Pluronic-type, nonionic surfactants suitable for use in various oral care products.

Hill et al., U.S. Pat. Nos. 4,950,479 and 5,057,309 disclose the claimed emulsions of the present invention in "liquid center chewing gums". However, there is no teaching or suggestion that the Hill et al. emulsions can be coated onto chewing gum and subsequently released into the oral cavity at a predetermined plaque disrupting level and rate.

One of the leading researchers in gum technology, the Wm. Wrigley Jr. Company, has contributed various innovations to chewing gum technology, including:

- the addition of lanolin and lecithin to chewing gum mixes to decrease tackiness and reduce cohesive properties, U.S. Pat. Nos. 2,197,718 and 2,197,719 respectively;
- the addition of certain paraffin waxes to chewing gum mixes imparts smoothness and freedom from tack, U.S. Pat. No. 2,137,746;
- chewing gum compositions possessing anticaries activity based on the addition of various aldehydic compounds to the gum base, U.S. Pat. No. 3,651,206;
- adhesive chewing gum compositions, U.S. Pat. No. 3,984,574, and
- a method of preventing tooth remineralization, U.S. Pat. No. 4,568,537.

The release of active ingredients from the gum base is a major problem and one which has confronted the industry for a long time despite the fact that slab chewing gums on a weight basis are more than 75% water soluble materials such as sugars, sugar substitutes, corn syrup, and the like.

It therefore has been the usual practice in the industry when manufacturing chewing gums having active ingredients to deposit the active ingredient upon the exterior of a gum nugget or center, usually with an underlying thin layer of hard sugar. The outer layer of hard sugar is generally produced by tumbling the units in coating pans into which saturated solutions of sugar are poured and the water driven out by aeration, the finished piece being commonly called "candy coated gum". The use of candy coated gum allows for the dissolution of the active ingredient in the mouth before it is chewed into the gum base. See U.S. Pat. Nos. 3,075,884 and 3,011,949. This method of production is costly and eliminates desired slab forms of gum containing such an active ingredient. See also U.S. Pat. Nos. 1,629,461, 1,771,982 and 2,198,165.

### SUMMARY OF THE INVENTION

It has now been found that chewing gums provided with a special coating as set forth herein, can provide inter alia, the following beneficial effects to the user; plaque disruption, gingivitis control, hypersensitivity treatment, stomatitis treatment, and the like. The chewing gums of the present invention are coated with an emulsion containing an ingestible surfactant and a polydimethyl siloxane emulsified therein. If desired, the emulsion coating can contain various therapeutic substances such as microbially active stannous fluoride, and the like.

One embodiment of the present invention combines two of the three primary elements of oral hygiene, namely surfactant-emulsifier cleansing and reduction of the surface energy required for plaque adherence by coating the tooth and oral tissue surfaces with the polydimethyl siloxane emulsified therein coupled with frequent cleansing to achieve plaque disruption. The unexpected plaque disrupting effect of the emulsion coated chewing gums of the present invention are obtained without antimicrobial ingredients and without altering the critically balanced microflora of the oral cavity.

A second embodiment of the present invention comprises the innovative coating processes used to lay down on the surface of the chewing gums the melt emulsions of the invention, wherein the melt emulsion coating substantially releases from the chewing gum into the oral cavity, shortly after chewing starts at a predetermined rate and in a predetermined amount.

A third embodiment of the invention comprises therapeutic chewing gums characterized by an emulsion coating as described earlier, wherein the emulsion coating contains a therapeutic substance such as stannous fluoride and the emulsion coating-therapeutic substance mixture is released into the oral cavity from the gum, during chewing, at a predetermined rate and in a predetermined amount. Other therapeutic substances include: oral care medicaments such as chlorhexidine, triclosan, potassium nitrate, various quaternaries, the active essential oils in Listerine®, and the like, various antibiotics, analgesics, oral discomfort relief active ingredients, and the like.

A fourth embodiment of the present invention comprises the methods of treating the oral cavity by chewing various emulsion coated gums and releasing various plaque disrupting and other therapeutic substances into the oral cavity from said gums at a predetermined rate and in a predetermined amount.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention comprises: a chewing gum coated with an emulsion of an ingestible surfactant or emulsifier and a polydimethyl siloxane insoluble in said surfactant or emulsifier, wherein the coating releases from the gum into the oral cavity during chewing, at an effective predetermined rate and in an effective predetermined amount.

Suitable surfactants and emulsifiers for use in the present emulsion coating for gum include:

sodium lauryl sulfate,  
sodium lauroyl sarcosinate,  
polyethyleneglycol stearate,  
polyethyleneglycol monostearate,  
coconut monoglyceride sulfonates,  
soap powders,  
sodium alkyl sulfates,  
sodium alkyl sulfoacetates,  
alkyl polyglycol ether carboxylates such as those described in U.S. Pat. No. 4,130,636,  
polyoxyethylene derivatives of sorbitan esters, such as those described in U.S. Pat. Nos. 3,639,563 and 3,947,570,  
propoxylated cetyl alcohols, such as those described in U.S. Pat. No. 2,677,700.

Particularly preferred surfactants include block copolymers comprising a congeneric mixture of conjugated polyoxybutylene and polyoxyethylene 1200 compounds having as a hydrophobe, a polyoxybutylene polymer of at least molecular weight; such as those described in U.S. Pat. Nos. 4,343,785, 4,465,663, 4,511,563 and 4,476,107.

These polymers are prepared by adding the required number of mols of propylene oxide to the two hydroxyl groups of propylene oxide to the two hydroxyl groups of propylene glycol to form a hydrophobic base and then adding ethylene oxide to both ends of the hydrophobic base to form hydrophilic polyoxyethylene groups of controlled length. Various species of such polymers, including those defined above as useful in the invention, are available commercially from Wyandotte Chemicals Corporation of Wyandotte, Mich. under the trademark "Pluronic."

Especially preferred are the commercially available surfactants which include the polyoxyethylene-polyoxybutylene block copolymers such as Pluronic F108, and F 127 (BASF) and polysorbates such as Tween 40, and 80, (Hercules.)

Suitable emulsifiers for use in the present emulsion coating include various polyethylene glycols commonly referred to as PEG and PEG oleate, PEG Beeswax, mono-methylether polyethylene glycol, and the like.

The polydimethyl siloxanes suitable for use in the chewing gum coatings of the present invention can be characterized as follows, they:

- (1) suppress the tendency of the surfactant cleaners present to foam;
- (2) are safely ingestible at the concentrations used;
- (3) have an affinity for mouth and teeth surfaces;
- (4) are neutral, inert and do not support biological activity;
- (5) modify the surface energy properties of surfaces of the mouth such that it is more difficult for food particles, cellular debris and various plaque precursors and formers to attach to these surfaces;

(6) form a thin, transparent coating that does not build up on mouth surfaces and is removed by the

various chewing gums of the present invention are described in Table 1 below.

TABLE I  
ILLUSTRATIVE EXAMPLES OF MICRODENT COATING MIXTURES  
(Percent by Weight)

Example	Surfactant	polydimethyl siloxane	sorbitol powder	sweeteners	flavor	mouthfeel agent	% by wt coated on gum
1	(1)F-127	(3)DC 360 @ 350 cs	none	none	none	none	1.5
	80.0	20.0					
2	F-127	DC 360 @ 1000 cs	20.0	saccharin	peppermint	carrageenan	2.1
	56.7	20.0		0.1	0.2	3.0	
3	F-127	DC 360 @ 12,500 cs	30.0	aspartame	Doublemint	none	3.0
	30.0	30.0		0.2	0.4		
4	(2)F-108	(4)Antifoam 1500	none	none	none	(5)Klucel MF	3.8
	20.0	30.0				2.0	
5	F-108	DC 360 @ 12,500 cs	59.8	aspartame	none	none	1.8
	20.0	20.0		0.1			
6	PEG 150	DC 360 @ 350 cs	32.0	none	spearmint	(6)Methocel K4M	4.3
	62.5	20.0			0.1	2.7	
7	PEG 100	DC 360 @ 12,500 cs	15.0	saccharin	IFF van-mint	carrageenan	5.6
	40.0	4.4		0.2	0.3	15.0	
					kaolin		
					25.3		
8	PEG 150-OLEATE	DC 360 @ 1000 cs	10.0	aspartame	IFF van-mint	Klucel MF	2.1
	70.0	14.0		0.2	0.2	5.6	
9	PEG 20-BEESWAX	DC 360 @ 1000 cs	none	saccharin	IFF tutti-frutti	none	2.8
	39.5	15.0		0.3	0.3		
	F-108	DC 360 @ 12,500 cs					
	30.0	15.0					

(1)Pluronic F-127(BASF) brand of poloxamer 407

(2)Pluronic F-108 (BASF) brand of poloxamer 338

(3)Dow Corning Medical Fluid 360 in various viscosity (cs) grades

(4)Dow Corning Food Antifoam 1500

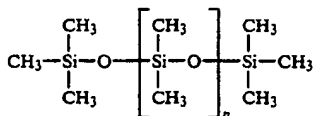
(5)Ethyl propyl cellulose (Aqualon)

(6)Carboxy methyl cellulose (Dow)

- normal clearing and flushing action of the mouth;  
(7) impart a pleasant "smooth" feeling to the surfaces of the mouth and teeth, and  
(8) are insoluble in the surfactant or emulsifiers used herein.

These polydimethyl siloxanes are commonly referred to as dimethicone or simethicone (when admixed with small amounts of silica) are commercially available from Dow Corning Corp., Midland, Mich. and other suppliers, in both food and medical grades. Polydimethyl siloxanes are water-white, viscous oil-like liquids. See Merck Index, 11th Edition, Monograph Number 8486 and R. R. McGregor's text "Silicones and Their Uses", McGraw-Hill (1954). See also, U.S. Pat. Nos. 2,441,098; 2,606,510 and 2,761,782.

Polydimethyl siloxanes suitable for the emulsion coatings of the present invention can be described by the general structure:



wherein n represents the number of repeating dimethyl siloxane units and can range from below 100 to several thousand. Typically, the molecular weight of these polydimethyl siloxanes are designated by their viscosity. Safety, efficacy and processing considerations suggest that viscosities from about 350 centistokes to 12,500 centistokes are preferred for the present invention.

Examples of various surfactant or emulsifier-polydimethyl siloxane emulsions suitable for coating

The concentration of the emulsion as a percent by weight of the gum to which it is applied can range from between about 0.5% by weight and about 6% by weight. Preferably the coating comprises from between about 1.0% and about 4.0% by weight of the gum. On an absolute weight basis, the coating may be applied in a range from between about 10 mg/piece to about 150 mg/piece. Preferably the coating can weigh from between 20 mg/piece and 100 mg/piece.

The chewing gum coated with the surfactant-emulsifier-polydimethyl siloxane emulsion is a typical chewing gum composition manufactured by utilizing conventional chewing gum manufacturing operations to which the innovative coating processes of the present invention are applied.

All manner of natural or synthetic gum bases are to be considered as included within the scope of the present invention. Examples of suitable gum bases include chicle, gutta percha, jelutong, balata, namaquand rubber, almeidana gum, abba rubber, gutta siak, gutta cotie, gutta kay, gutta hangkang, gutta penang, and yellow gutta. Further examples of gum bases include rosins, such as comarone resin, pontianak resin, copal gum, kauri gum, dammar gum, sweet bay gum, spruce gum, and balsams. Moreover, suitable gum bases include crown gum, nisperio, rosidinha, pendare, perillo, niger gutta, and tuno.

Additional chewing gum base materials include elastomers such as polyisobutylene, polyisoprene, isobutyleneisoprene copolymers and copolymers of butadiene and styrene, hydrogenated or partially hydrogenated vegetable oils such as soy bean, cotton seed, corn, peanut, and palm or animal fats such as tallow and lard. In addition paraffin, beeswax, petroleum wax,

polyethylenes, and polyvinylacetates may be employed. Further descriptions of suitable chewing gum bases are found in U.S. Pat. No. 2,366,589 issued to Borglin Jan. 2, 1945; U.S. Pat. No. 3,821,417, issued to Westall, et al. on Jun. 28, 1974; U.S. Pat. No. 4,041,179 issued to Stubits et al. on Aug. 9, 1977; U.S. Pat. No. 3,984,574 issued to Comollo on Oct. 5, 1976 and U.S. Pat. Nos. 1,807,704 and 2,076,112 all of which are hereby incorporated herein by reference.

Further descriptions of suitable chewing gum bases are found in U.S. Pat. No. 4,357,355, to E. Koch et al., U.S. Pat. No. 4,387,108, to E. Koch et al., and U.S. Pat. No. 4,518,615, to S. R. Cherukuri et al., all of which are hereby incorporated herein by reference.

The gum base referred to above covers the nonnutritive, masticatory substance in chewing gum, as defined in the Federal Food, Drug and Cosmetic Act. In the regulation covering chewing gum ingredients under the Food Additives Amendment (Federal Register, p. 4419, May 9, 1962), paragraph (a) sets forth the ingredients permitted in chewing gum base under the regulation, and paragraph (c) defines the term "chewing gum base" as non-nutritive masticatory substance comprised of one or more of the ingredients named and so defined in paragraph (a) of this section. Suitable representative chewing gum bases which can be employed with facility in formulating the chewing gum compositions of the invention are those disclosed, for example, in U.S. Pat. No. 2,284,804 of F. T. De Angelis and U.S. Pat. No. 2,137,746 of R. L. Wilson, U.S. Pat. No. 2,383,145 of J. E. Moose, U.S. 2,288,100 of G. J. Manson and U.S. Pat. Nos. 2,366,589; 3,821,417; 4,041,179 and 3,984,574, all of which are hereby incorporated herein by reference.

The coated chewing gum products of the present invention are pleasant to use. The various flavors in the emulsion coatings of the present invention are formulated to be as pleasant as a good quality chewing gum and to contribute this pleasant taste over a longer-than-expected time period thus enhancing the "its working" perception without negative medicinal connotations which are found to reduce frequency of use and undermine the frequent cleansing advantage of previous therapeutic chewing gums. The feeling in the mouth is equally pleasant. A smooth, "something's happening" feeling is perceived immediately upon the start of chewing, followed by a clean, fresh, well lubricated mouth and tooth surface which unexpectedly persists much longer than traditional uncoated chewing gums.

The combination of certain surfactants and/or emulsifiers with certain polydimethyl siloxanes wherein the latter is inherently insoluble in the former, in a coating on a chewing gum is novel. The plaque disrupting results obtained with chewing gum containing this coating is novel. Furthermore, the surfactant-polydimethyl siloxane-saliva mixture obtained in the mouth is ingestible and can be pleasantly swallowed, which further distinguishes this plaque fighting gum from typical plaque fighting products such as dentifrices used with a toothbrush and most rinses and prerinses. For example, unlike typical surfactants used in dentifrice pastes, the surfactants of the present invention do not fill the mouth with foam and can be pleasantly swallowed which is necessary for the high frequency cleaning feature of the coated chewing gums of the present invention.

Surprisingly, the surfactant and/or emulsifier polydimethyl siloxane combination of the present invention retains good surface active properties and is able to clear the mouth of some cell debris, food debris, mate-

rial alba, sugars, starches and other precursors to plaque. This surfactant-emulsifier cleaning from the coating chewing gums of the present invention is obtained with minimal foaming while simultaneously coating the surfaces of the oral cavity with a thin neutral film containing the plaque disrupting active ingredients of the composition. This neutral film is not metabolizable by resident oral cavity microorganisms. By contrast, natural film formers such as lecithin-containing substances and fats are known to form anti-attachment films on mouth surfaces but these films are not suitable for the purposes of the present invention since they are metabolizable and are not neutral. Most of these naturally occurring coating substances support biological activity rather than form non-supportive inert films and as such, work opposite of the suitable film formers of the present invention. See for example; Menaker, The Biologic Basis of Dental Caries, Chapter 16; Gibbons and Hoote, Ann. Rev. of Microbiol., 29 pp. 19-44; and Hayes, J. Dent. Res., 632, pp. 2-5 (1984).

As long as this transient inert coating in the oral cavity obtained from the coated chewing gums of the present invention remains, it:

1. restricts the subsequent adherence of plaque forming materials to the teeth, thus continuing the disruption of plaque formation;
2. continues to impart a "smooth" feeling to the mouth, prolongs the flavor perception of the coated chewing gums of the present invention, and
4. reduces the "fatigue" and "tired of chewing gum" factor, allowing for longer pleasure and contact time for various therapeutic substances which may be included in the coating.

Most users of the coated chewing gums of the present invention perceive a quite different feeling in the mouth than is perceived with typical chewing gums. For example,

1. the mouth feels exceptionally clean and smooth and the surfaces of the teeth are slick and shiny. This well lubricated feeling of the mouth is particularly beneficial to mouth breathers and those afflicted with mouth dryness;
2. the prolonged flavor perception is generally described as "freshness": and persists much longer with the compositions of the present invention than when the same flavor is introduced into the mouth in the form of a conventional uncoated chewing gum. This residual flavor benefit is an important element contributing to frequency of use, and
3. prior to swallowing the surfactant-polydimethyl siloxane coating, saliva mixture that is released during chewing of the gum, the user perceives that the combination is "doing something" in the mouth. This perceived signal of efficacy reinforces repeat usage and often motivates the user to a more frequent use pattern, a key element in maximizing the efficacy of the present invention. This increased frequency of use is perceived as a major advance in oral care compliance and should be welcomed by most oral care professionals.

Combining the various cleaning-coating-mouth-feeling benefits of the surfactant-polydimethyl siloxane emulsions compositions of the invention with a chewing gum, provides for the first time, a commercializeable product whose form of delivery works in conjunction with the product to be dispensed to promote frequent use i.e. frequent cleansing and plaque fighting. As noted above, infrequent cleansing remains as the major road

block to effective oral hygiene. Effective but socially inconvenient toothpaste, mouth rinses, and prerinses are simply not used with the frequency required to obtain optimum interruption of plaque formation.

Frequency of cleansing is encouraged by the two unique characteristics of the coated chewing gums of the present invention. These cause the user to return to the invention frequently throughout the day, stimulated as much by enjoyment, as by conscious recall of "my mouth needs cleaning" after events such as meals, snacks, coffee breaks, drinks, smokes, and the like.

The therapeutic chewing gums of the present invention are characterized by an emulsion coating as described earlier, wherein the emulsion coating contains one or more therapeutic substances. At the outset of chewing the coated gum, the coating-therapeutic substance(s) mixture is released from the surface of the chewing gum into the oral cavity at a controlled rate and in a predetermined amount.

Therapeutic substances suitable for use in the emulsion coated chewing gums of the present invention include:

various antimicrobials,  
microbially active stannous fluoride,  
chlorhexidine,  
triclosan,  
various zinc compounds, including zinc chloride,  
cationic antimicrobial agents including various quaternaries such  
as cetylpyridinium chloride,  
the essential oils in Listerine®,  
stearoyl-2-1-actate,  
antioxidants including various aldehydic compounds as well as  
propyl gallate,  
various enzymes,  
various antibiotics including tetracycline,

metronidazole,  
strontium chloride,  
potassium nitrate,  
carrageenan,  
cough and cold remedies, and the like.

Other substances which may also be included in the chewing gum base mixture and which may also be added to the emulsion coating include: non toxic sources for acid such as adipic acid in combination with calcined kaolin, calcium carbonate, sodium carbonate, sodium bicarbonate, various phosphates, dicalcium phosphate, tetra sodium pyrophosphate, lecithin, lanolin, hydrolyzable tannin, silica, and the like.

The various therapeutic additives which can be included in the emulsion coatings of the present invention have traditionally been used to treat various oral care conditions as well as other health concerns. For example, microbially active stannous fluoride is a well known for treating gingivitis, hypersensitivity and stomatitis. See Hill et al., U.S. Pat. Nos. 5,057,310; 5,098,711 and 5,165,913.

The relatively fast rate of release from the coated chewing gum of the emulsion coating-microbially active stannous fluoride mixture into the oral cavity would be an effective means for introducing controlled and efficacious levels of the microbially active stannous ion into the oral cavity. The pleasant tasting chewing gum encourages compliance and accordingly repetitive treatments throughout the day can be expected; thereby accommodating the fairly limited substantivity of the antimicrobial moiety, the stannous ion, to the oral mucosa.

Various emulsion coating compositions of the present invention containing various therapeutic substances and suitable for coating the chewing gums of the present invention are described in Table II below along with the oral condition to be treated.

TABLE II

THERAPEUTIC CHEWING GUMS						
Type of Therapeutic Substance Added to Emulsion Coating (% by weight)						
EXAMPLE	Coating Mixture From Table I (qs to 100%)	Abrasive for cleaning and tartar control	Antimicrobial	Antibiotic	Dry Mouth	Oral Discomfort
10.	#1	silica dentifrice grade (10-30)				
11	#3		stannous fluoride (1.2-4.0)			
12	#4				Mineral salts (saliva equiv.) sodium fluoride (2 ppm - final)	
13	#5			tetracycline (0.5-2.5)		
14	#6					benzocaine (4.0-10.0)
15	#5					potassium nitrate (5.0)
16	#3					pectin (5.0-15.0)
17	#8		triclosan (0.2-1.0)			
18	#9	Kaolin (10-30)				

mineral salts,  
remineralization substances,  
pectin,  
benzocaine,  
analgesics, for mouth & throat discomfort,  
sanguinarine extract,

The coating compositions of the invention may also contain certain phosphate salts, such as tetrasodium or tetrapotassium pyrophosphate(s), which have been shown to aid in the control of plaque and the calcified plaque called tartar.

The high flavor levels which can be pleasantly incorporated into emulsion coatings of this invention, whose frequent application is encouraged by the unique character of the invention, and which are retained in the mouth for surprisingly long time periods also contribute to the plaque controlling properties of this invention. For example, natural and synthetic flavor and sweetener agents as diverse as menthol, xylitol and glycyrrhizin are known to be beneficial towards plaque control and are included in the emulsion coating compositions of this invention (see, e.g., Segal, J. Pharm. Sci., 74 pp. 79-81 (1985) and Makkinen, J. Am. Dent. Assoc. III, pp. 740-741).

In addition to the coating compositions described above, preferred embodiments of the coatings use various viscosity control agents to impart certain viscosity characteristics to the coatings of the invention. It is believed that in these preferred embodiments of the invention, viscosity plays a role in achieving optimum mouth feel and flavor retention characteristics of the invention.

The conventional flavoring components suitable for the emulsion coatings of the present invention are exemplified by the following materials, menthol, anise oil, benzaldehyde, bitter almond oil, camphor, cedar leaf oil, cinnamic aldehyde, cinnamon oil, citronella oil, clove oil, eucalyptol, heliotropin, lavender oil, mustard oil, peppermint oil, phenyl salicylate, pine oil, pine needle oil, rosemary oil, phenyl salicylate, pine oil, thyme oil, thymol, wintergreen oil, lemon and orange oils, vanillin, and other flavoring oils generally regarded as safe (GRAS) by health authorities.

Additional adjuncts can be added to the emulsion coatings to provide color, flavor, or sweetening effects, as desired. Examples of suitable sweetening agents include sorbitol, sodium cyclamate, saccharine, commercial materials such as Nutrasweet® brand of aspartame and xylitol. If desired, the coloring agent is typically added in an amount of 0.01 percent to about 0.02 percent by weight. Citric acid is often utilized as a flavor additive. All types of flavoring materials are generally used in amounts of about 0.01 to about 5.0 percent by weight, preferably about 0.05 percent to about 3.0 percent by weight.

A buffering ingredient may also be added to the emulsion coating compositions of the invention in order to prevent natural degradation of the flavoring components. Generally, the Ph of these compositions is adjusted to 3.5 to about 7, preferably from about 5 to about 6. The buffering ingredients such as an alkali metal salt of a weak organic acid, for instance, sodium benzoate, sodium citrate, sodium phosphate, or potassium tartrate is generally added in an amount of about 0.1 to about 1.0 percent by weight.

In addition to the buffering ingredients, the compositions of the invention can optionally contain at least one humectant selected from the group consisting of glycerine, xylitol, sorbitol and propylene glycol. Generally, the liquid humectants are utilized in the proportion of about 3 percent to about 12 percent by weight based upon the total weight of the composition. Preferably, the liquid humectant is utilized in an amount of about 3 to 4 percent weight of the coating emulsion.

Solid humectants can be utilized at levels from about 1% by weight to about 50% by weight, thereby imparting a broad range of delivery, mouthfeel and taste properties.

More particularly, the chewing gums of the present invention comprise in the range of about 15% to about 60% by weight gum base. Several formulations are possible, depending upon the type of gum desired (i.e., sugar-containing or sugarless chewing gums, conventional stick gums, or bubble gums). Suitable raw materials for gum bases include chicle, latex, RBH resin, crown gum, Malsa compound PU-C, picolyte resin, candelilla wax, chiquibil gum, and the like.

Conventional chewing gum bases that may be obtained from commercial suppliers are generally suitable.

Suitable conventional stick gum bases (i.e., as opposed to bubble gum bases) include "Paloja"; "Firm Paloja"; "Berguna"; and "Dreyco," all available from the L.A. Dreyfus Corporation, P.O. Box 500, South Plainfield N.J., and "Synthetic Base No. 2939" and "Natural Base No. SC319," which can be obtained from the American Chicle Company, New York, N.Y.

In general, "Paloja," "NOVA" and "Dreyco" are preferred chewing gum bases.

Suitable bubble gum bases include: "D.C."; "Extra Soft"; "Oak"; "Grande"; "Soft Ideal"; "Ideal"; "Model"; and "Ladco," all available from the L.A. Dreyfus Corporation.

Other examples of such materials may be found in Vol. 30 of the U.S. Federal Register, No. 247, Sec. 121.1059, dated Dec. 23, 1965.

The gum base will also include a flavoring in an amount ranging from about 0.3 to about 1.5% by weight and preferably from about 0.8 to about 1.2% by weight of the final chewing gum product. The flavoring may comprise oils derived from plants, leaves, flowers, and the like. Representative flavor oils of this type include essential oils such as peppermint oil, spearmint oil, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, cedar leaf oil, cinnamon oil, oil of nutmeg, oil of sage, oil of bitter almonds, cassia oil, and methylsalicylate (oil of wintergreen), and also include citrus oils such as lemon oil, orange oil, lime oil, grapefruit oil, fruit essences such as apple essence, pear essence, peach essence, strawberry essence, apricot essence, raspberry essence, cherry essence, plum essence, pineapple essence, watermelon, banana and the like; bean-derived flavors, such as coffee, cocoa and the like; wine-derived flavors, such as curacao, and the like; and pungent materials, such as affinin, pepper, mustard and the like.

The sweetening agent ingredient used in the chewing gum bases of this invention may be selected from a wide range of materials, including water-soluble sweeteners, water-soluble artificial sweeteners, and dipeptide based sweeteners, including mixtures thereof. Without being limited to particular sweetening agents, representative illustrations encompass:

- A. Water-soluble sweetener such as monosaccharides, disaccharides, and polysaccharides such as xylose, ribose, glucose, mannose, galactose, fructose, dextrose, sucrose, maltose, partially hydrolyzed starch or corn syrup solids and sugar alcohols such as sorbitol, xylitol, mannitol, hydrogenated glucose syrup and mixtures thereof, and
- B. Water-soluble artificial sweeteners such as the soluble saccharin salts, i.e., sodium or calcium saccharin salts, cyclamate salts, such as the sodium salt and the like, and the free acid form of saccharin; dipeptide based sweetening agents such as L-aspartyl-L-phenyl-alanine methyl ester and materials described in U.S. Pat. Nos. 3,492,131 and 3,642,491 and the like; dihydrochalcone; glycyrrhizin; Stevia

*rebaudiana* (Stevioside); and the synthetic sweetener 3,6-dihydro-6-methyl-1,2,3-oxathiazin-4-one-2,2-dioxide, particularly the potassium (Acesulfame-K), sodium and calcium salts thereof, as described in German Pat. No. 2,001,017.7.

The use of xylitol in various products such as chewing gums is reported in U.S. Pat. No. 3,296,079 to Griffin, issued Jan. 3, 1967; U.S. Pat. No. 3,655,866, issued to Bilotti on Apr. 11, 1972; U.S. Pat. No. 3,914,434 issued to Bohni on Oct. 21, 1975; U.S. Pat. No. 4,000,320 issued to Klose, et al on Dec. 28, 1976 and U.S. Pat. No. 3,899,593 issued to Hammond et al., on Aug. 12, 1975.

The effect of chewing gums containing xylitol and sorbitol on plaque formation is discussed in Caries Res. 17:569-378 (1983), and in JADA, Vol. 108, 587-592 (1984).

In those instances where the sweetening agent chosen provides more than bulk or texture, such as where the artificial sweeteners of Category B above are used, the term sweetening agent, for purposes of this invention, is meant to include artificial sweeteners and bulk sweeteners. Typical bulk sweeteners such as one or more sugar alcohols, including sorbitol, mannitol, xylitol and the like, or mixtures thereof, are utilized in amounts of about 20% to about 70%, preferably about 30% to about 60% by weight, together with one or more of the artificial sweeteners described in Category B above, which artificial sweeteners are utilized in amounts of about 0.05% to about 0.3%, preferably about 0.18% to about 0.22%, by weight, all percentages being based on the weight of the total composition.

In a preferred embodiment of this invention, the sweetening agent used is a combination of an artificial sweetener such as sodium saccharin, and bulk sweeteners such as mannitol, sorbitol, and hydrogenated glucose syrup, generally in amounts of 0.05% to about 0.3%, preferably about 0.18% to about 0.22% artificial sweetener; about 2% to about 15%, preferably about 4% to about 8% mannitol; and about 20% to about 50%, preferably about 30% to about 40% sorbitol, and about 20% to about 50%, preferably about 30% to 40% hydrogenated glucose syrup with the total bulk sweetener content being from about 30% to about 60% depending upon the effect desired, all percentages being by weight, based on the weight of the total chewable tooth cleaning composition is preferred, the sweetening agent used in the practice of this invention may include sugar as well as an artificial sweetener.

The combination of artificial sweeteners and bulk sweeteners used in this invention generally provides approximately equivalent levels of bulk and sweetness as do the saccharide type of sweeteners in category A above. The amounts of sweetening agents described above are ordinarily necessary to achieve a desired level of sweetness independent of the flavor level achieved from the inclusion of flavoring agents.

Yet another desirable ingredient in the composition of the present invention is the use of glycerin. In the chewing gum aspect of the present invention glycerin serves to soften and maintain the chewability of the chewing gum for prolonged periods. The glycerin also adds to the sweetness of the composition. The glycerin is ordinarily added at levels of from about 0.2% to about 5% by weight of the composition.

Plasticizing-softening agents commonly used in the chewing gum compositions are suitable for use in the practice of this invention, including lanolin, propylene glycol, glycerol, acetylated monoglyceride, glyceryl

triacetate, glyceryl diacetate, fatty acids, lecithin, glycerin, and the like and mixtures thereof. In a preferred embodiment, a combination of acetylated monoglyceride, lecithin and glycerin can be used, generally in amounts of about 0.5% to about 0.5% acetylated monoglyceride, about 0.1% to about 0.7% lecithin and about 2.0% to about 15.0% glycerin; preferably about 0.1% to about 0.3% acetylated monoglyceride, about 0.4% to about 0.6% lecithin and about 7.0% to about 9.0% glycerin, percents being by weight, based on the weight of the total chewable tooth cleaning compositions.

The coating process used with the chewing gums of the present invention allows the therapeutic emulsions to:

- a. be applied to conventional chewing gum in a controlled means,
- b. be released at a substantially constant, therapeutically effective, dosage level from the chewing gum during chewing,
- c. be released at a substantially constant therapeutically effective release rate from the chewing gum during chewing,
- d. substantially avoid being entrapped and/or bound in the chewing gum base during chewing,
- e. be applied to conventional chewing gum while avoiding interfering with chewing gum manufacturing processes, and
- f. be applied to chewing gum without negatively effecting the hedonic properties of said gum.

A unique feature of the chewing gum coating process of the present invention is that the melt-emulsions can be applied to the chewing gum utilizing a variety of coating techniques including printing, film making, adhesive application and textile dyeing processes. Each of these coating applications can be used to deliver controlled quantities of melt emulsions to the surface of gum to achieve plaque disruption effects when these coated gums are chewed.

Each of the coatings obtained from these various applications can be laid down on the gum surface in a pattern and in color such that the coating per se' is distinctive from its chewing gum substrate. The patterns and designs useful for these coatings include stripes, cross hatch designs, random markings and the like, all of which effectively communicate the plaque fighting and other therapeutic attribute of the coated chewing gums.

Alternatively the coatings of the melt emulsions of the present invention can be made indistinguishable from the gum surface. This attribute is particularly important when the melt emulsion contains a therapeutic substance prescribed for treating a youngster and the parent does not wish to alarm the youngster that a medicine is being chewed.

Additionally, the melt-emulsion coatings of the present invention can be applied to the surface of the chewing gum as a raised, distinctive "rib" of active ingredients. Again these raised coatings serve as a signal to the consumer of the plaque fighting and/or other therapeutic attributes of the chewing gum.

The emulsion of polydimethyl siloxane in surfactant or emulsifier is obtained by heating the requisite quantity of surfactant and polydimethyl siloxane together in an oil bath controlled at between about 100° C. and about 170° C. As the surfactant or emulsifier melts, the mixture easily emulsifies with moderate stirring into a uniform "cream". This "cream" is beneficially emulsified into smaller emulsion particle size by use of conven-

tional high shear mixing devices such as homomixers, high power-small orifice devices and the like.

Additional materials required can be blended into the melt-emulsion, again with moderate stirring. Due to the volatility of the various flavor oils that can be used, it may be desirable to cool the hot melt emulsion slightly while retaining fluidity before adding the flavor oils. Details of preparing these melt emulsions are described in the various examples below.

The chewing gum is prepared following accepted chewing gum processing as generally described in the various U.S. Patents referenced above. The chewing gum in sheet or slab form is cooled before the emulsion is applied to the chewing gum surface via the various coating processes of the present invention as described below.

Various embodiments of the invention can be employed to lay down a coating of the melt emulsion on the sheets of chewing gum. Such coating means generally do not interfere with the manufacturing and processing equipment used to manufacture sheets of chewing gum. Ideally, one or more of the chewing gum coating processes disclosed in the examples below can be retrofitted into most existing gum manufacturing equipment and processes.

The preferred coating processes used in the present invention are derivations of: printing, film making, adhesive coating and textile dyeing which until now have not been applied to the coating of heated melt emulsions to chewing gums.

The present invention will be further illustrated with reference to the following examples which will aid in the understanding of the present invention, but which are not to be construed as limitations thereof. All percentages reported herein, unless otherwise specified, are percent by weight. All temperatures are expressed in degrees Celsius.

#### EXAMPLE 1

Emulsions for use in coating the chewing gums of the invention are prepared as follows:

A. The ingestible nonionic surfactant, Pluronic F-127, 560 g, and polydimethyl siloxane, Dow Corning 360 Medical Fluid, 1000 CS. viscosity, 200 g, are heated to 150° C. with constant mixing using a lightning mixer. The heated emulsion is then transferred to a homomixer for 15 minutes, while the temperature is increased to 180° C.

The emulsion is cooled to 130° C. and the following is added with conventional mixing: insoluble saccharin, 1 g, peppermint oil, 0.2 g, and carrageenan powder, 30 g. This melt emulsion is poured onto a flat surface and cooled until solid. The solid emulsion is broken up into workable pieces or flaked using a doctor blade in a standard flaking operation. The flaked emulsion is stored until needed for preparing formulations as described in Tables I and II, and various examples below.

B. 200 g of the ingestible nonionic surfactant, Pluronic F-108, and 200 g of the polydimethyl siloxane, Dow Corning 360 Medical Fluid at 12,500 CS., are heated to 165° C. with constant overhead stirring using a lightning mixer. The mixture is transferred to a homomixer for 15 minutes. While the temperature is increased to 190° C. In a separate vessel, dry powdered sorbitol, 200 g, was melted and heated to 150° C. with mixing. The molten sorbitol was added to the homomixer containing the surfactant-polydimethyl siloxane emulsion and emulsified into said emulsion, forming a

three phase melt emulsion. The three phase melt emulsion is mixed with a homomixer for 15 minutes.

The melt emulsion is either poured onto a flat surface for cooling, until solid or chilled and flaked on a cold roller flaker. The resulting solids can be stored until needed for remelting, with or without therapeutic additives such as described in Table II. These therapeutic substances are added to the emulsion using heating and mixing to effect uniform dispersion in the emulsion.

Examples 2 through 6 below describe various coating processes used to coat sheets of commercial chewing gum with the emulsions described in Examples 1A and 1B.

#### EXAMPLE 2

The solid, flaked emulsion described in Example 1A was melted at 130° C. and forced through a heated orifice of 0.010 inches diameter under constant pressure onto a mixing sheet of gum. Following the orifice was a distributor blade of such configuration that a uniform bead of the heated emulsion was coated onto the sheet of chewing gum in the shape of a stripe dependent upon the distributor blade configuration and pressure.

The resulting application provided a single striped surface coating of the emulsion of approximately 10 mg by weight (0.4% of gum weight).

Increasing the orifice to 0.020 inches produced a  $\frac{1}{2}$  inch stripe of emulsion coating on the chewing gum sheet, approximately 40 mg by weight. The control of: orifice size, pressure, speed of the moving sheet of gum and configuration of distributor blade produced a wide range of emulsion coatings on the chewing gum. The resulting stripes are flexible, do not separate from the gum when handled and upon chewing the various striped coatings are released from the gum at a controlled rate and in a controlled amount. The released coatings are immediately deposited on the teeth and mucosa imparting a slick, just-brushed feeling to the mouth, which historically is associated with delivery to the mouth of these emulsions: using other delivery systems such as sprays and dental floss.

#### EXAMPLE 3

The solid emulsion prepared according to Example 1B was melted at 110° C. and coated onto an embossing print roller at the same temperature and rolled across a sheet of chewing gum. The emulsion coating was transferred from the heated roller to the cool sheet of gum essentially in the configuration of the print roller. The embossed pattern of emulsion coating, upon cooling did not come off the gum when handled. Upon chewing, the coated gum sample was perceived as similar to the sample described in Example 2.

#### EXAMPLE 4

A Slidex WAXMASTER™ adhesive coater Model 400 was filled with emulsions prepared according to Examples 1A and 1B, to which had been added a variety of flavors, sweeteners, mouth feel agents and therapeutic substances as described in Tables I and II. These various emulsions melted at 100° C. and were picked up by the coating roller at the same temperature. The quantity of each emulsion coating applied to the roller is controlled by a doctor blade fixed at varying distances from the roller.

As the gum sheet is moved past the coating roller by a second roller positioned immediately above the coating roller with a gap equal to or slightly less than the

gum sheet thickness; the hot emulsion is transferred to the cool gum sheet at varying thicknesses ranging from between about 0.001 and about 0.006 inches. The emulsion is coated onto the gum surface with whatever pattern is on the surface of the coating roller.

This technique as well as the other examples herein provide for any desired mg quantity of the active ingredient on a wide range of piece size and shape, for example, from "mini's" to regular (about 2.5 g) sticks to bubble gum slabs (about 10 g).

#### EXAMPLE 5

Using the same apparatus described in Example 4, the doctor blade is notched with notches ranging from 0.001 to 0.010 inches in each location that a coating stripe is desired on the chewing gum surface. The remainder of the doctor blade makes clean contact with the coating roller so as to produce quantitative stripes of desired width and thickness. The resulting striped emulsion coated chewing gum samples are perceived to be similar to those described in Example 2 above.

#### EXAMPLE 6

Using the apparatus described in Example 4 where the coating roller is modified with grooves 0.002 to 0.010 inches deep by 0.125 inches wide with the remainder of the doctor blade making clean contact with the coating roller, produces a quantitative stripe of the desired width and thickness. The resulting striped coated emulsion chewing gum samples are similar to those described in Example 2.

#### EXAMPLE 7

Samples of a coated therapeutic chewing gum were prepared according to the process described in Example 4 where the emulsions contained from between about 1.2 and about 4.0% by weight microbially active stannous fluoride. The coated gums were chewed and were perceived to be similar to those described in Example 2 above.

The various coated chewing gums of the invention produced according to Examples 1-7 above were observed to release a substantial amount of the coating at the outset of chewing with a resultant therapeutic effect.

The present invention has been described in detail, including the preferred embodiments thereof. However, it will be appreciated that those skilled in the art, upon consideration of the present disclosure, may make modifications and/or improvements on this invention and still be within the scope and spirit of this invention as set forth in the following claims.

What is claimed is:

1. A therapeutic preparation effective in treating localized conditions of the mouth, teeth and gums, said conditions being selected from the group consisting of plaque, gingivitis, hypersensitivity, stomatitis and microbes in the mouth, said preparation being in the form of a chewing gum wherein:

A. the chewing gum is coated with an emulsion comprising an ingestible surfactant-emulsifier and a polydimethyl siloxane insoluble in said surfactant-emulsifier,

B. the emulsion is applied to the chewing gum by means of a coating process selected from the group of coating processes consisting of printing, film coating, adhesive applications and textile dyeing, and

C. the emulsion coating on said gum is releasable during chewing, at a therapeutic effective rate and in a therapeutic effective amount.

2. The therapeutic preparation according to claim 1, wherein the emulsion coating comprises a therapeutic substance selected from the group consisting of antimicrobials, microbially active stannous fluoride, chlorhexidine, triclosan, zinc chloride, cationic antimicrobial agents, cetylpyridinium chloride, antioxidants, propyl gallate, enzymes, antibiotics, tetracycline, mineral salts, pectin, strontium chloride, potassium nitrate, metronidazole benzocaine, analgesics for mouth and throat discomfort, sanguinarine extract, stearyl-2-lactate, cough and cold remedies, and remineralizing substances.

3. The therapeutic preparation according to claim 1, wherein said coating releases during chewing at an effective plaque disrupting rate and in an effective plaque disrupting amount.

4. The therapeutic preparation according to claim 2, wherein the emulsion coating comprises microbially active stannous fluoride, releasable at an effective antigingivitis rate and in an effective antigingivitis amount.

5. The therapeutic preparation according to claim 2, wherein the emulsion coating comprises microbially active stannous fluoride releasable at an effective hypersensitivity treatment rate and in an effective hypersensitivity treatment level.

6. The therapeutic preparation according to claim 2, wherein the emulsion coating comprises microbially active stannous fluoride releasable at an effective stomatitis treatment rate and at an effective stomatitis treatment level.

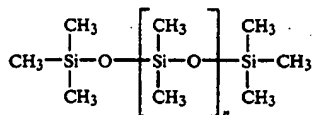
7. The therapeutic preparation according to claim 2, wherein the emulsion coating comprises chlorhexidine releasable at an effective gingivitis treatment rate and at an effective gingivitis treatment level.

8. The therapeutic preparation according to claim 2, wherein the emulsion coating comprises triclosan releasable at an effective gingivitis treatment rate and at an effective gingivitis treatment level.

9. The coated chewing gum according to claim 1, wherein the ingestible surfactant is selected from the group consisting of:

sodium lauryl sulfate,  
sodium lauryl sarcosinate,  
polyethylene glycol stearate,  
polyethylene glycol monostearate,  
coconut monoglyceride sulfonates,  
block copolymers of polyoxyethylene and polyoxybutylene,  
alkylpolyglycol ether carboxylates,  
polyethylene derivatives of sorbitan esters,  
propoxylated cetyl alcohol,  
block copolymers comprising a congeneric mixture of conjugated polyoxybutylene and polyoxyethylene compounds having as a hydrophobe a polyoxybutylene polymer of at least 1200 molecular weight,  
a salt of a fatty acid (soap powder), and emulsified polyethylene glycols, polyethylene glycol oleate, polyethylene glycol beeswax and monomethyl ether polyethylene glycol.

10. The coated chewing gum according to claim 1, wherein the polydimethyl siloxane has the general structure:



wherein n represents a whole number from between about 100 and 5,000, and the polydimethyl siloxane has a viscosity from between about 350 and about 12,500 centistokes.

11. A coated chewing gum according to claim 1, wherein the coating is applied to the chewing gum at from between about 0.5% and about 6% by weight of the gum, or from between about 10 mg/piece and about 100 mg/piece.

12. A coated chewing gum according to claim 9, wherein the ingestible surfactant is a polyoxyethylene-polyoxybutylene block copolymer.

13. A chewing gum according to claim 3, wherein the plaque disrupting, emulsion coating is applied to the chewing gum at an elevated temperature by means of a printing process.

14. A chewing gum according to claim 3, wherein the plaque disrupting, emulsion coating is applied to the chewing gum at an elevated temperature by means of a film coating process.

15. A chewing gum according to claim 3, wherein the plaque disrupting, melt-emulsion coating is applied to the chewing gum at an elevated temperature by means of an adhesive application process.

16. A chewing gum according to claim 3, wherein the plaque disrupting, emulsion coating is applied to the chewing gum at an elevated temperature by means of a textile dyeing process.

17. A method of manufacturing a therapeutic chewing gum comprising, preparing a sheet of chewing gum, coating said sheet of gum with an emulsion maintained at a temperature between about 100° C. and about 200° C., wherein:

- a. the emulsion comprises an ingestible surfactant or emulsifier and a polydimethyl siloxane insoluble in said surfactant or emulsifier, and
- b. the coating process is selected from the group of coating processes consisting of printing, film making, adhesive applications and textile dyeing.

\* \* \* \* \*

**EXHIBIT D**

**U.S. Patent No. 6,030,605 to D'Amelia, et al.**



US006030605A

**United States Patent** [19]**D'Ameila et al.**[11] **Patent Number:** **6,030,605**[45] **Date of Patent:** **Feb. 29, 2000**[54] **BREATH FRESHENING COMPOSITIONS  
AND METHODS USING THEM**

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[21] Appl. No.: **09/227,704**

[22] Filed: **Jan. 8, 1999**

**Related U.S. Application Data**

[63] Continuation-in-part of application No. 08/832,103, Apr. 3, 1997, abandoned.

[51] Int. Cl.<sup>7</sup> ..... **A61K 9/20**; **A61K 9/68**;  
..... **A61K 31/315**

[52] U.S. Cl. .... **424/48**; **424/440**; **424/441**;  
..... **424/464**; **424/641**; **424/642**; **424/643**

[58] Field of Search ..... **424/48**, **440**, **441**,  
..... **424/464**, **641**, **642**, **643**

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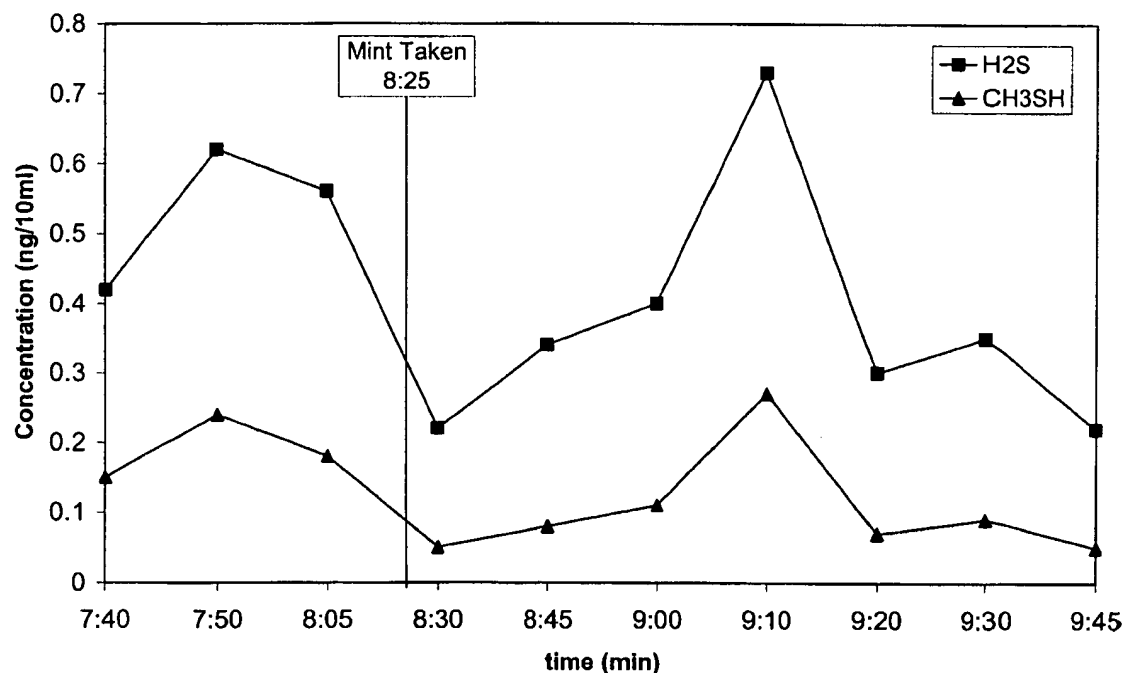
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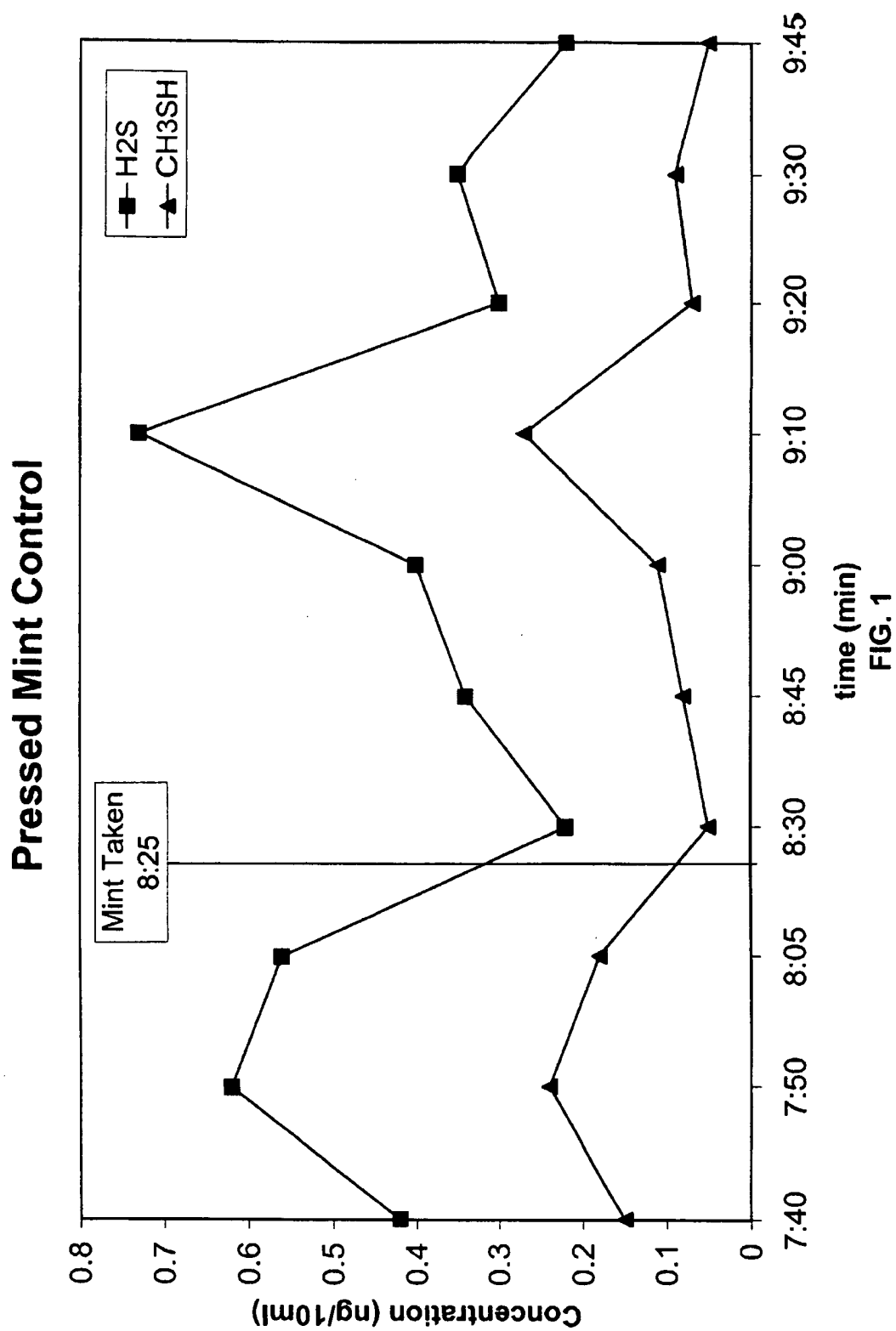
*Primary Examiner*—Shep K. Rose

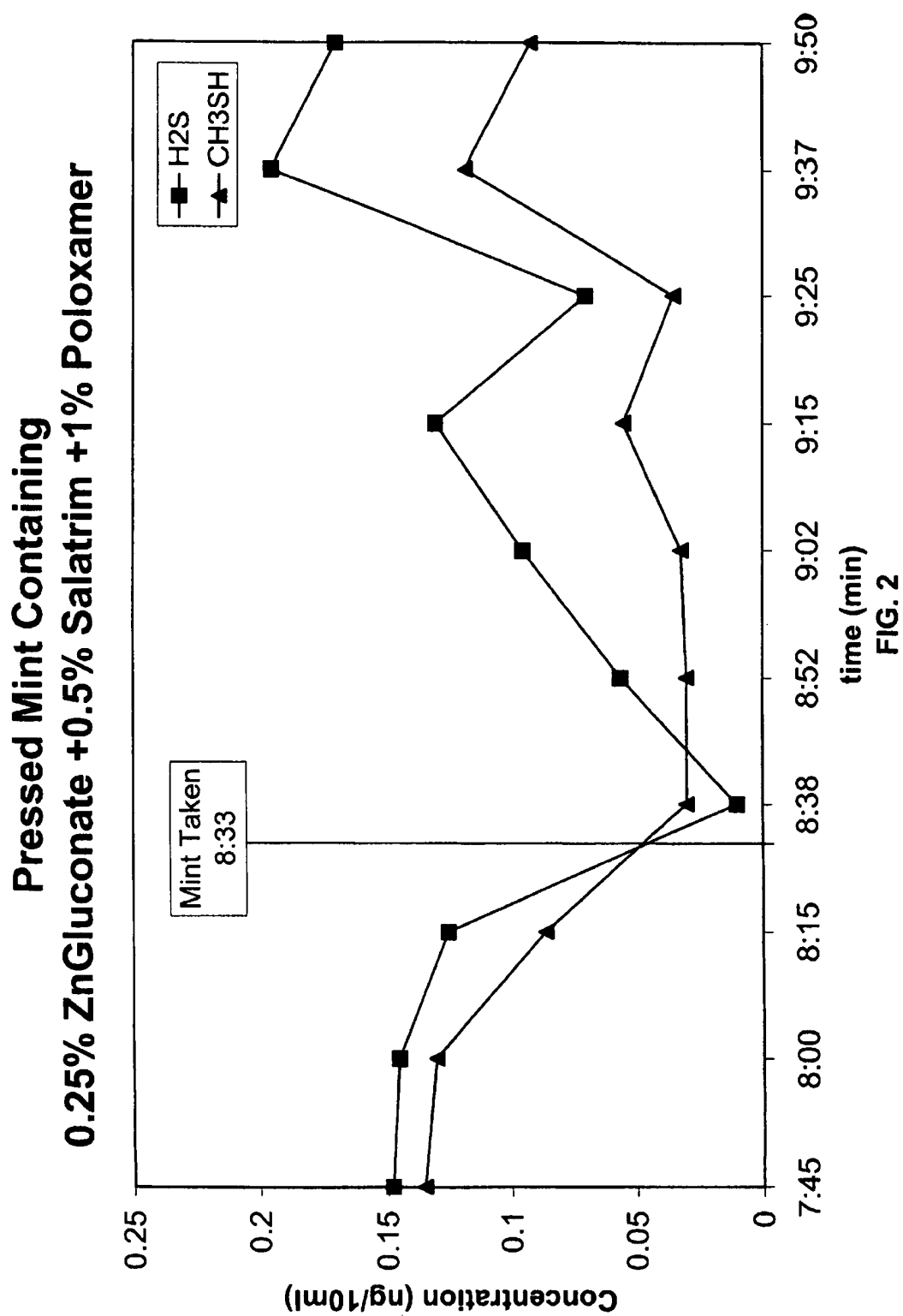
*Attorney, Agent, or Firm*—Scully, Scott, Murphy & Presser

[57] **ABSTRACT**

The present invention is directed towards the use of chewing gums, tablets and lozenges containing a breath freshening composition which comprises a physiologically acceptable zinc compound, an oil, and a non-ionic surfactant, to reduce or eliminate H<sub>2</sub>S and CH<sub>3</sub>SH in the oral cavity.

**15 Claims, 17 Drawing Sheets****Pressed Mint Control**





**Pressed Mint Containing  
0.5% ZnGluconate +1% Salatrim +2% Poloxamer**

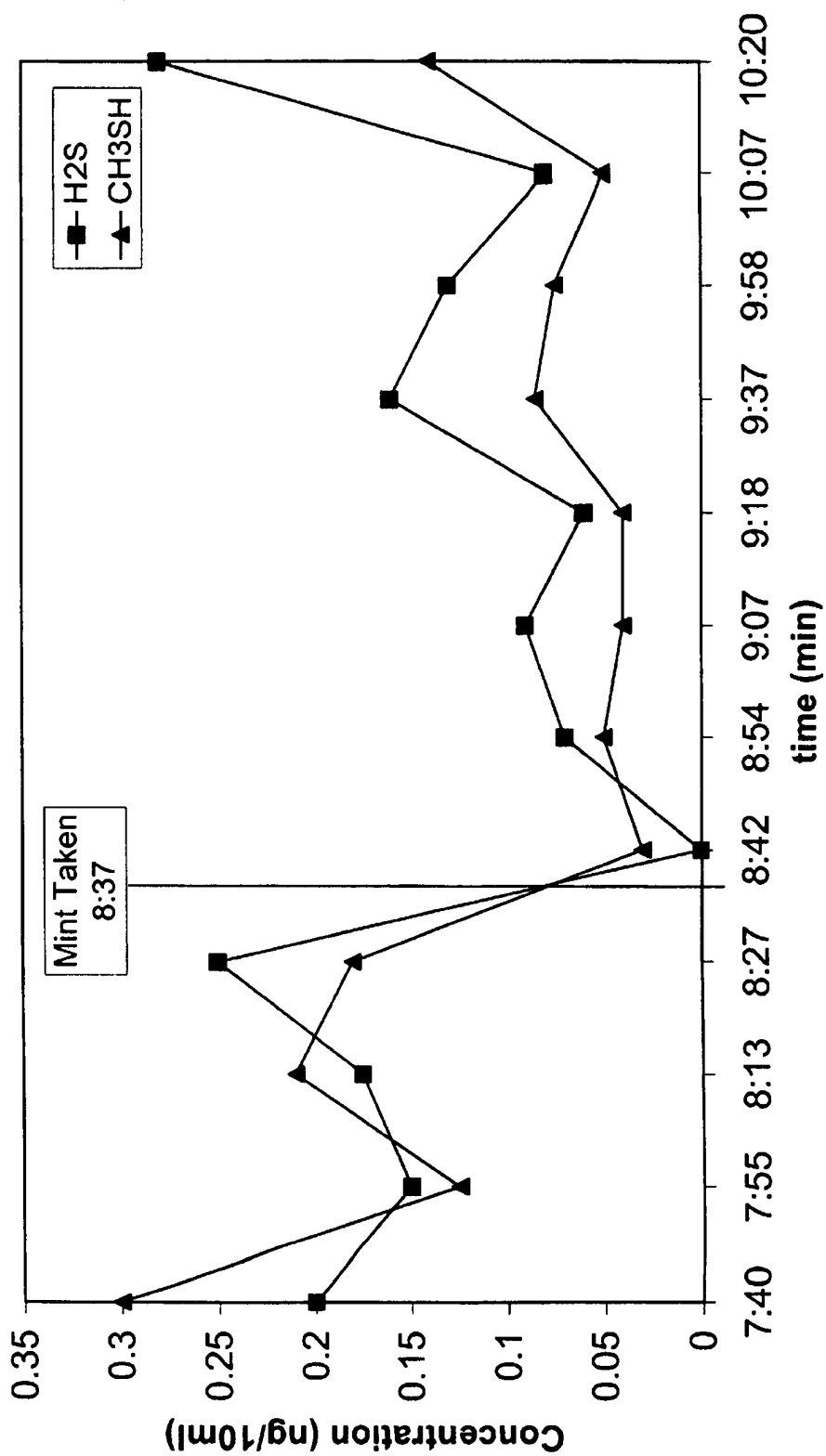


FIG. 3

**Pressed Mint Containing  
0.25% ZnGluconate +0.5% Canola Oil +1% Poloxamer**

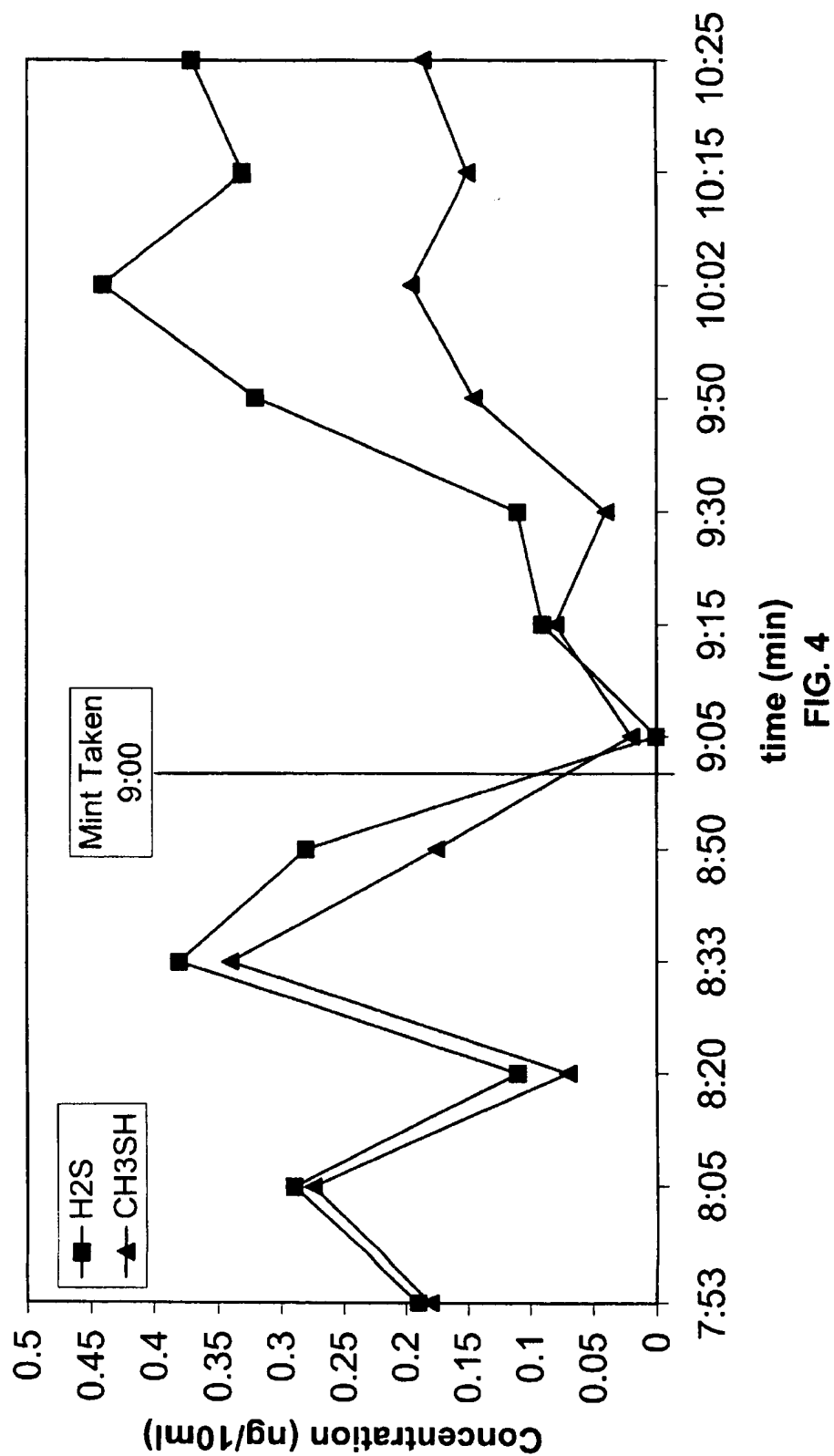


FIG. 4

**Pressed Mint Containing  
0.5% ZnGluconate +1% Canola Oil +2% Poloxamer**

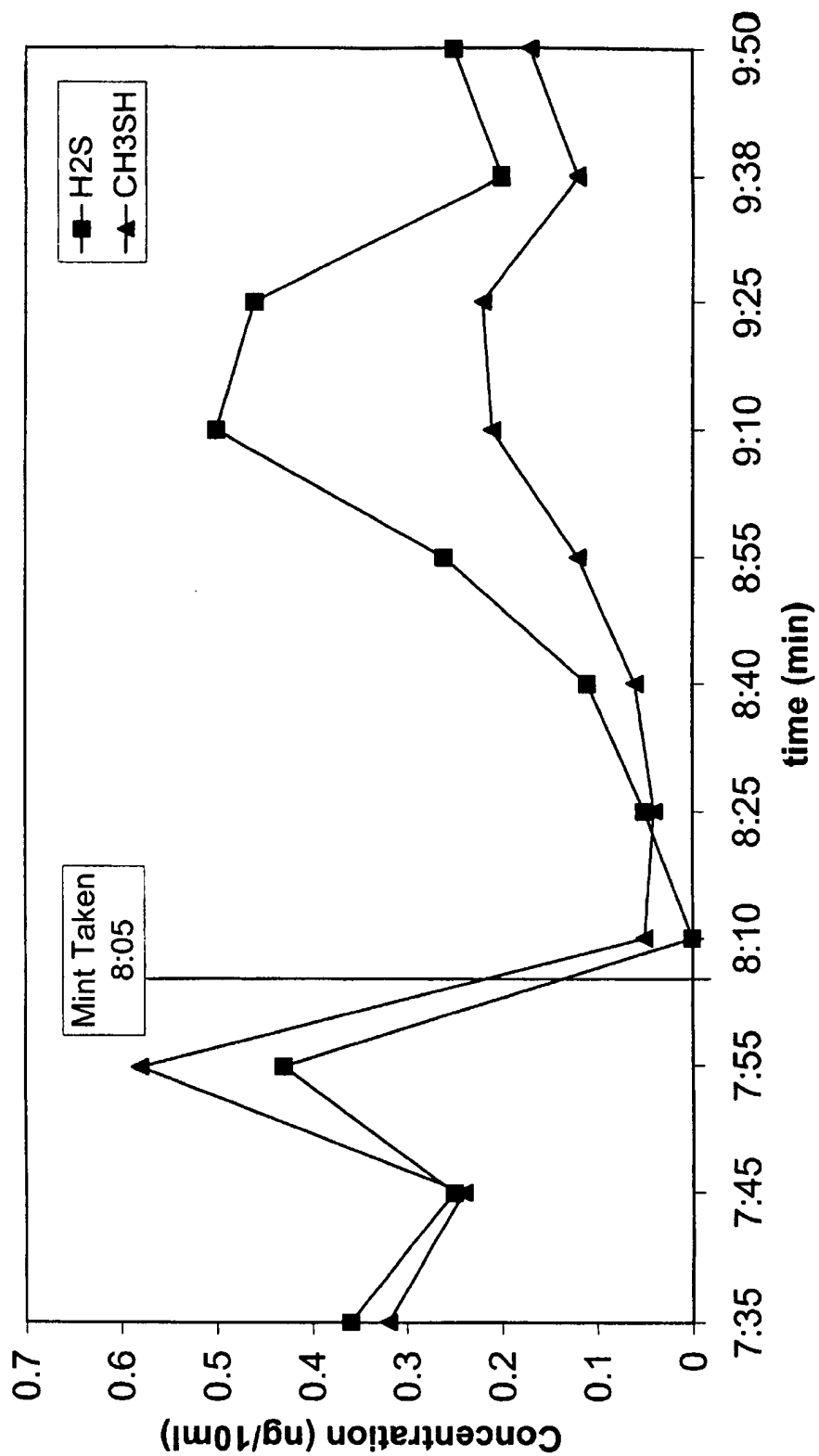
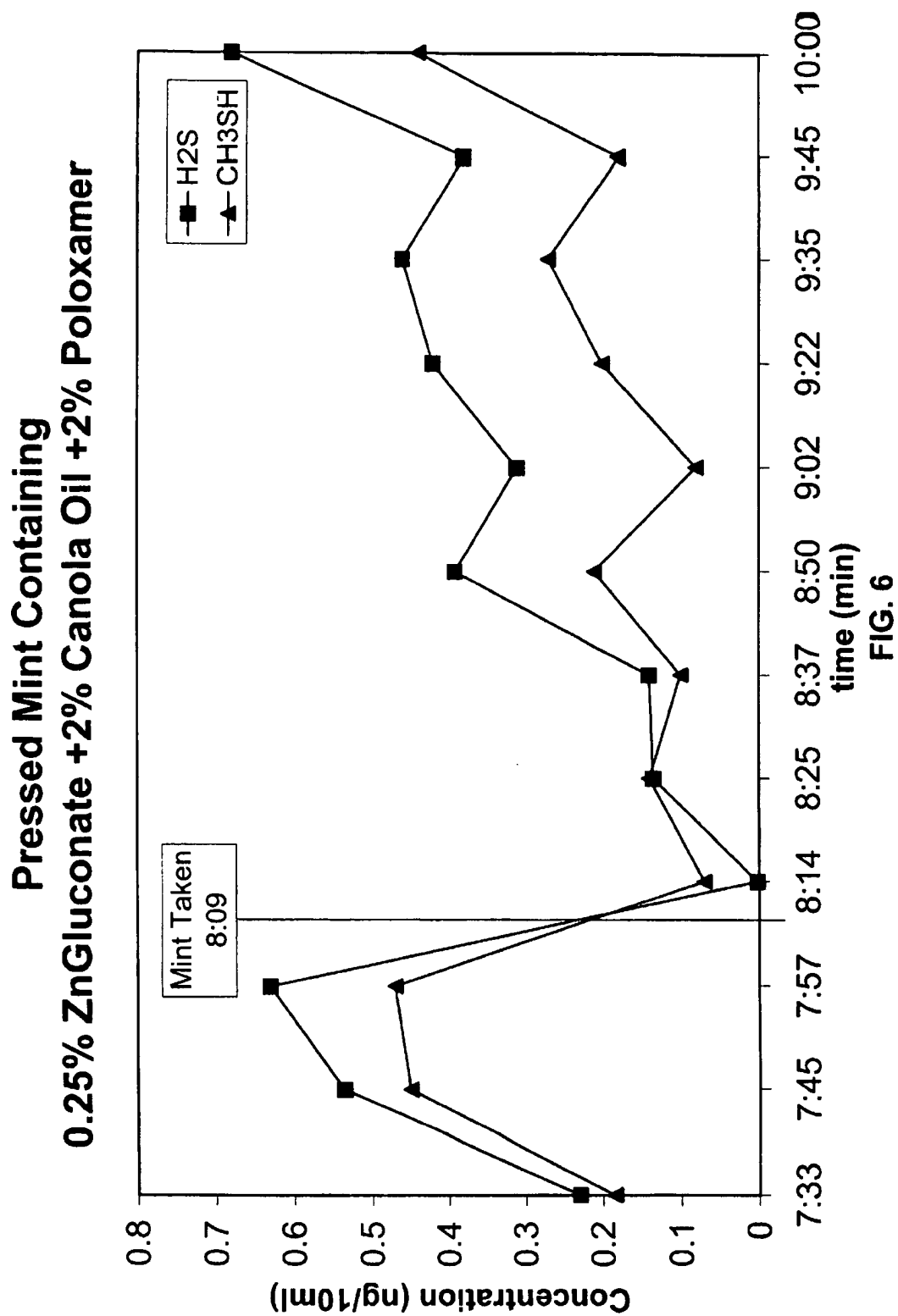


FIG. 5



**Pressed Mint Containing  
0.25% ZnGluconate +2% Canola Oil +1% Poloxamer**

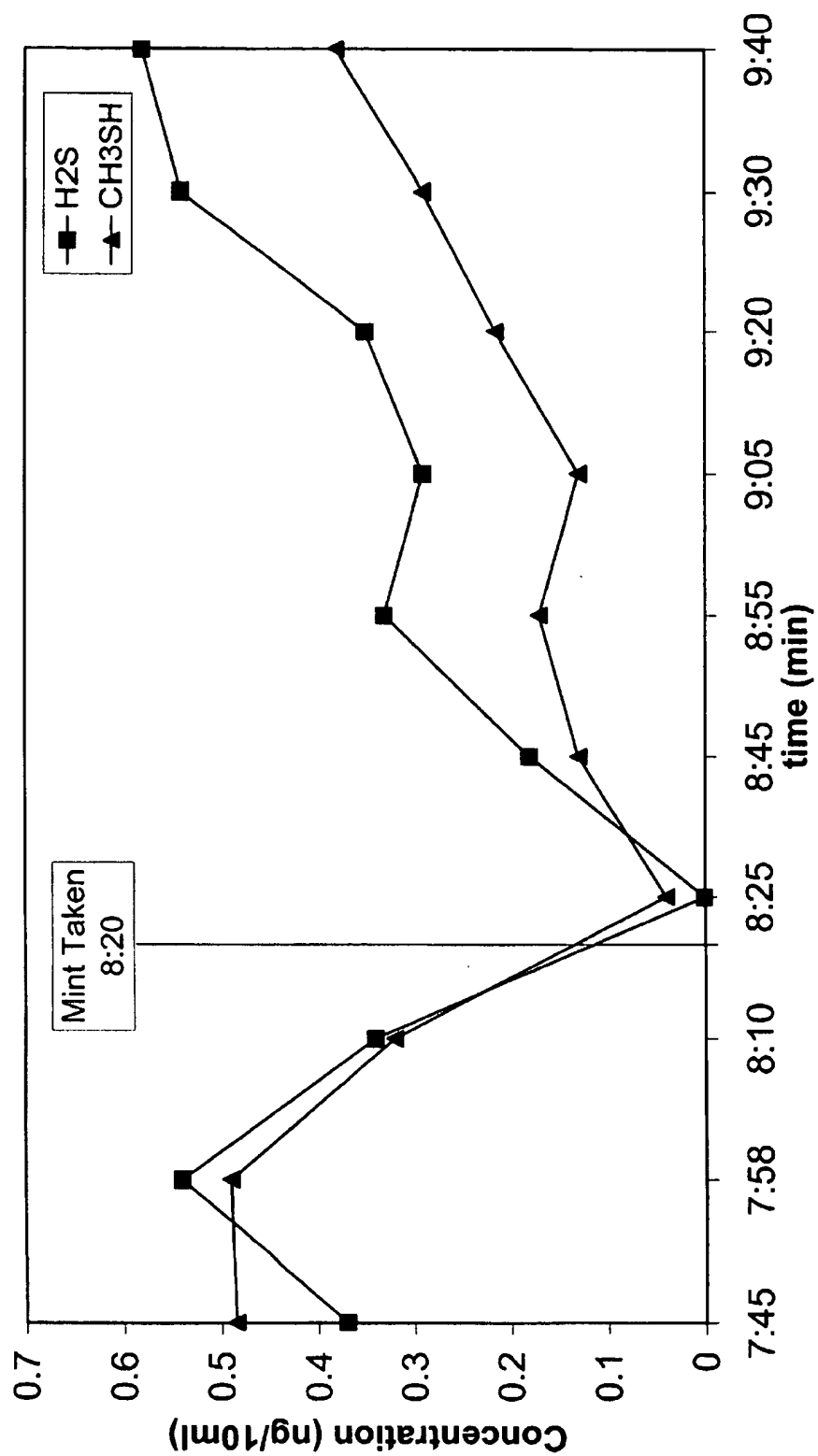
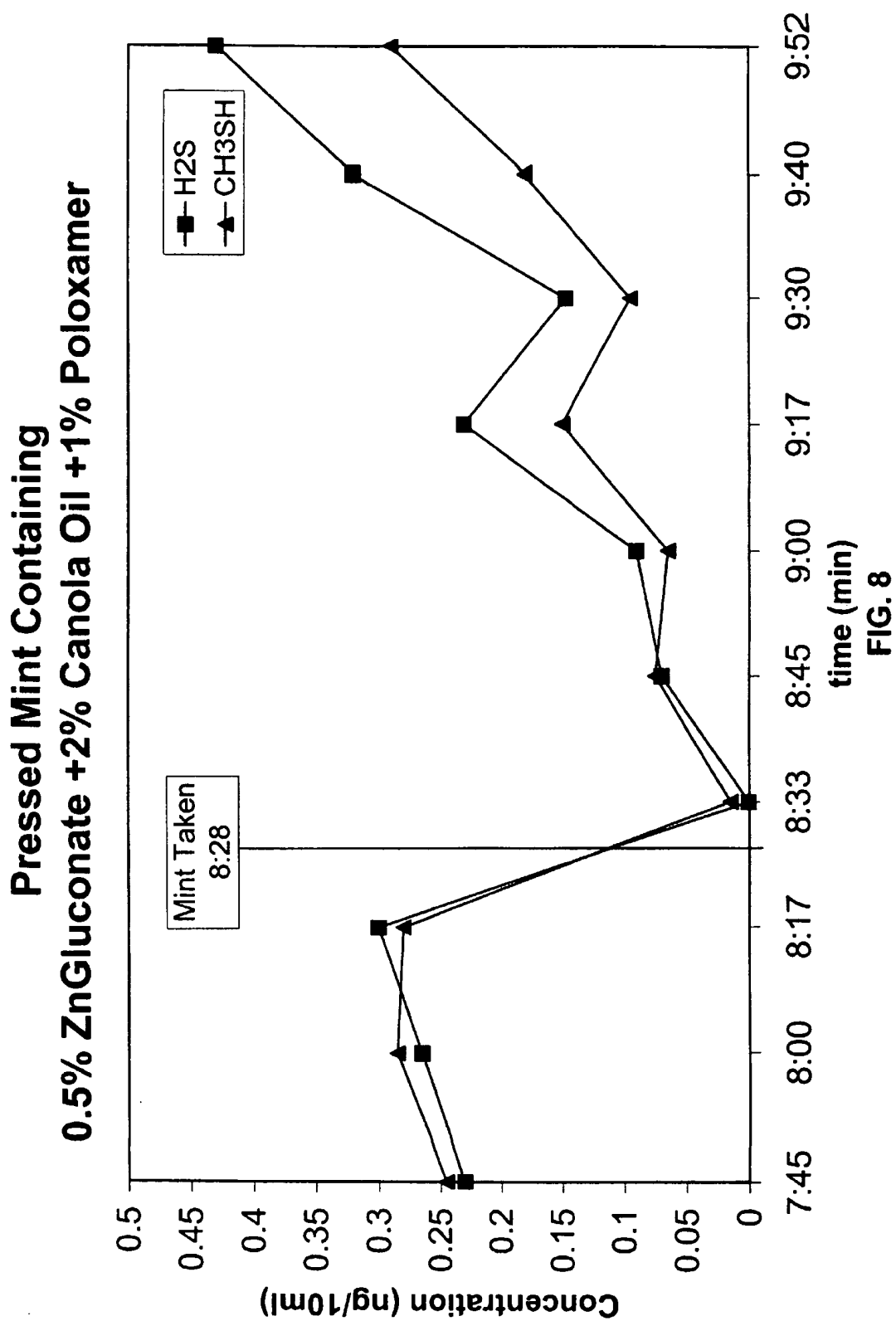
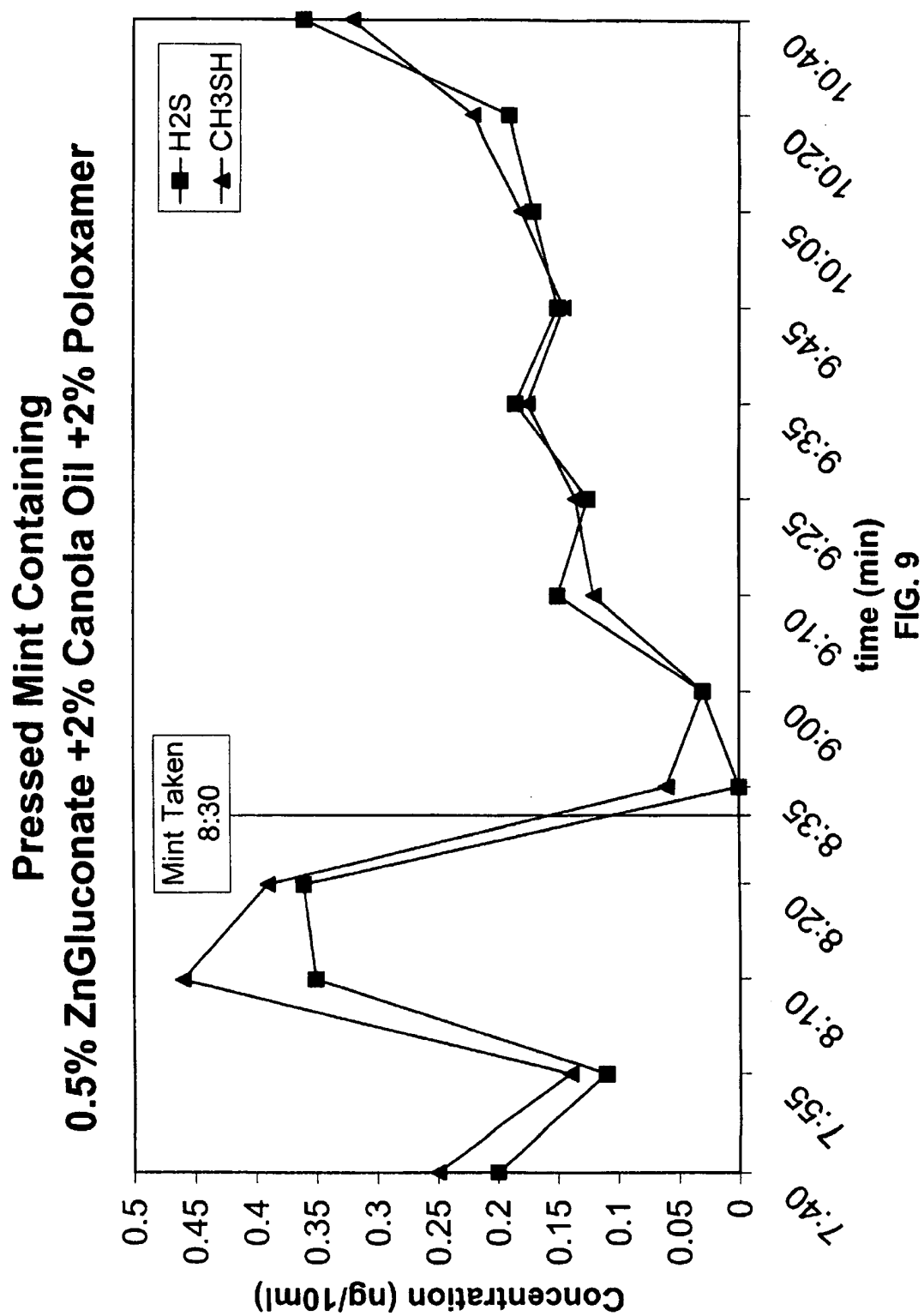
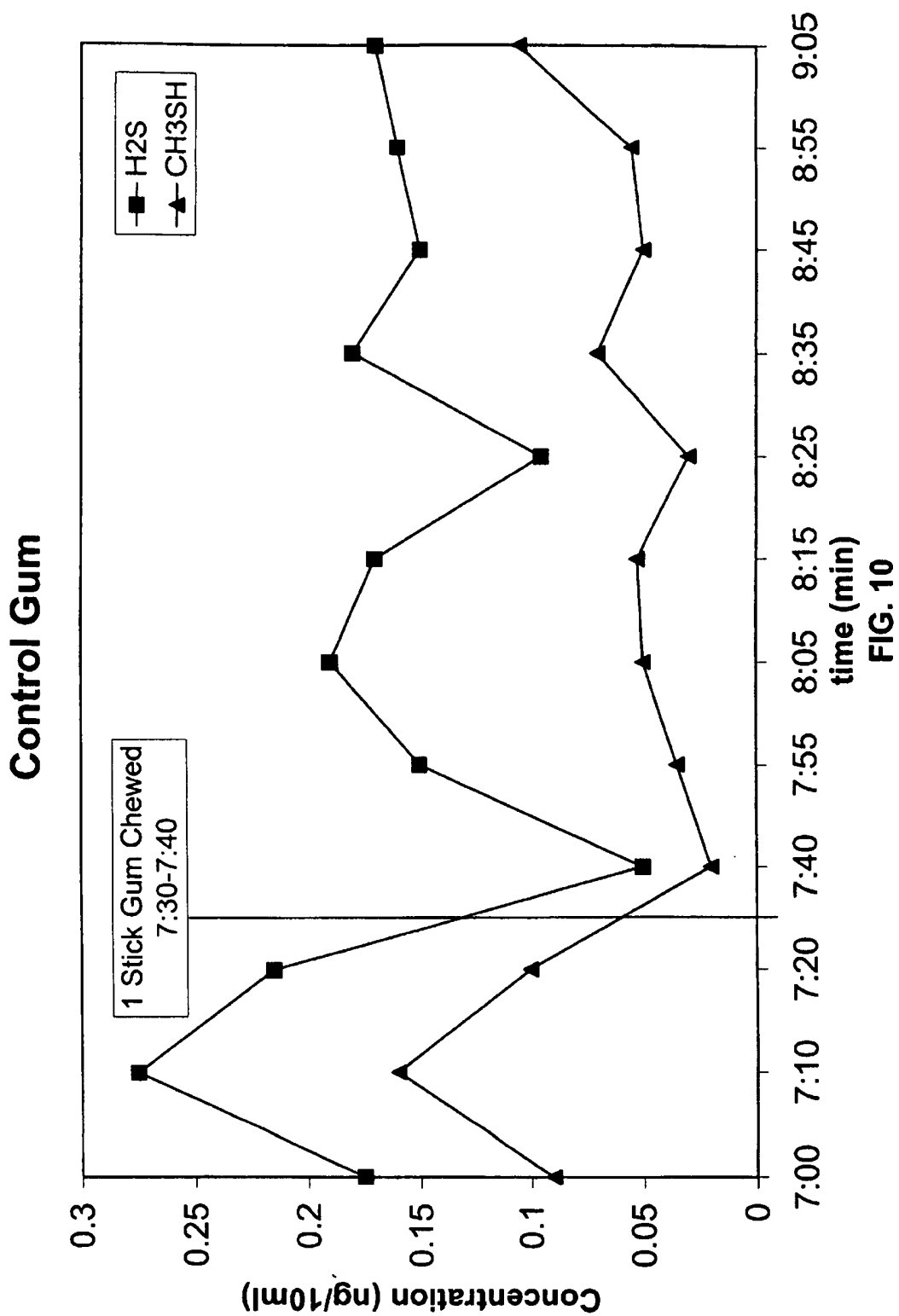


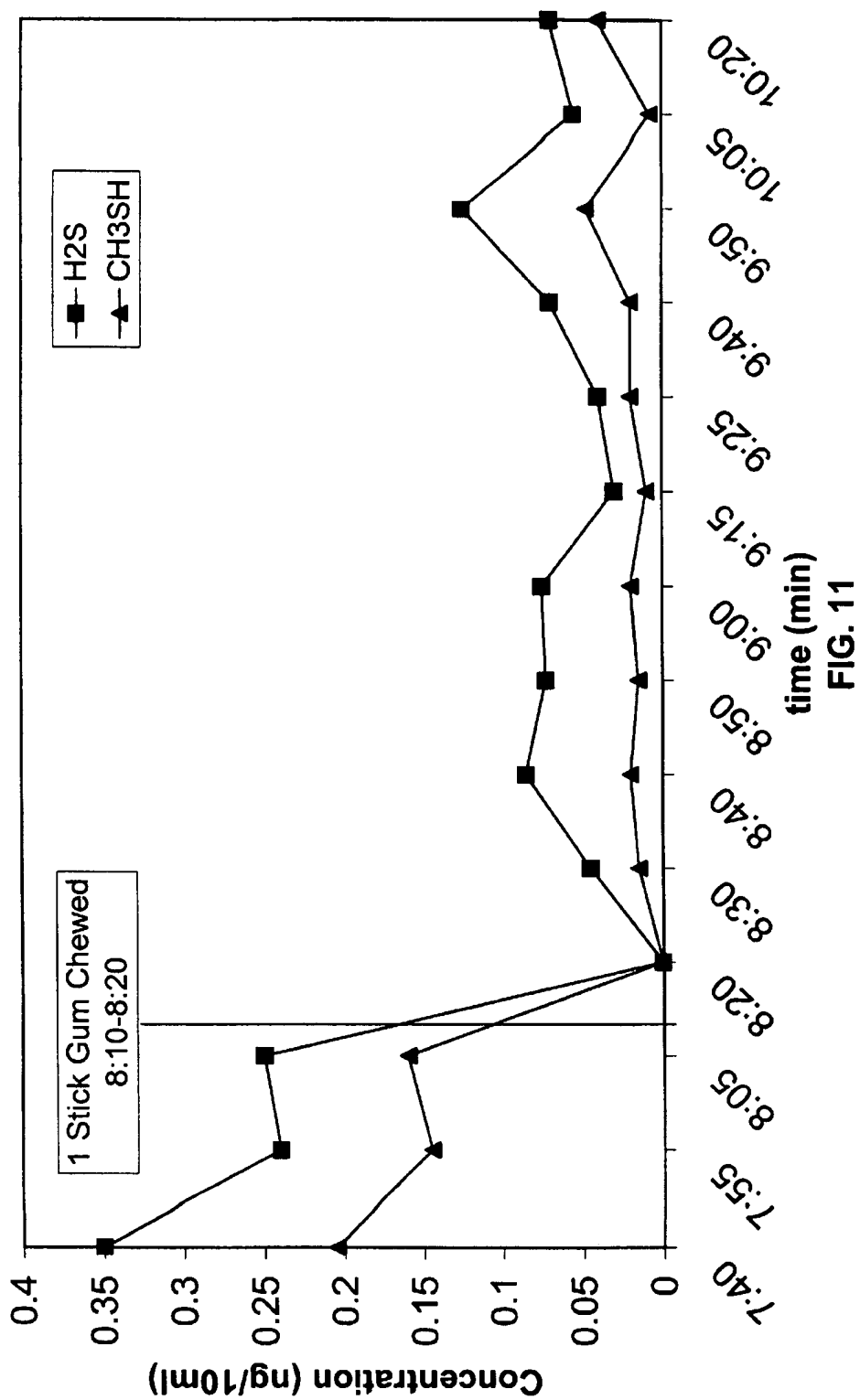
FIG. 7







**Chewing Gum Containing  
0.25% ZnGluconate +1% Canola Oil +1% Poloxamer**



**Chewing Gum Containing  
0.5% ZnGluconate +2% Canola Oil +2% Poloxamer**

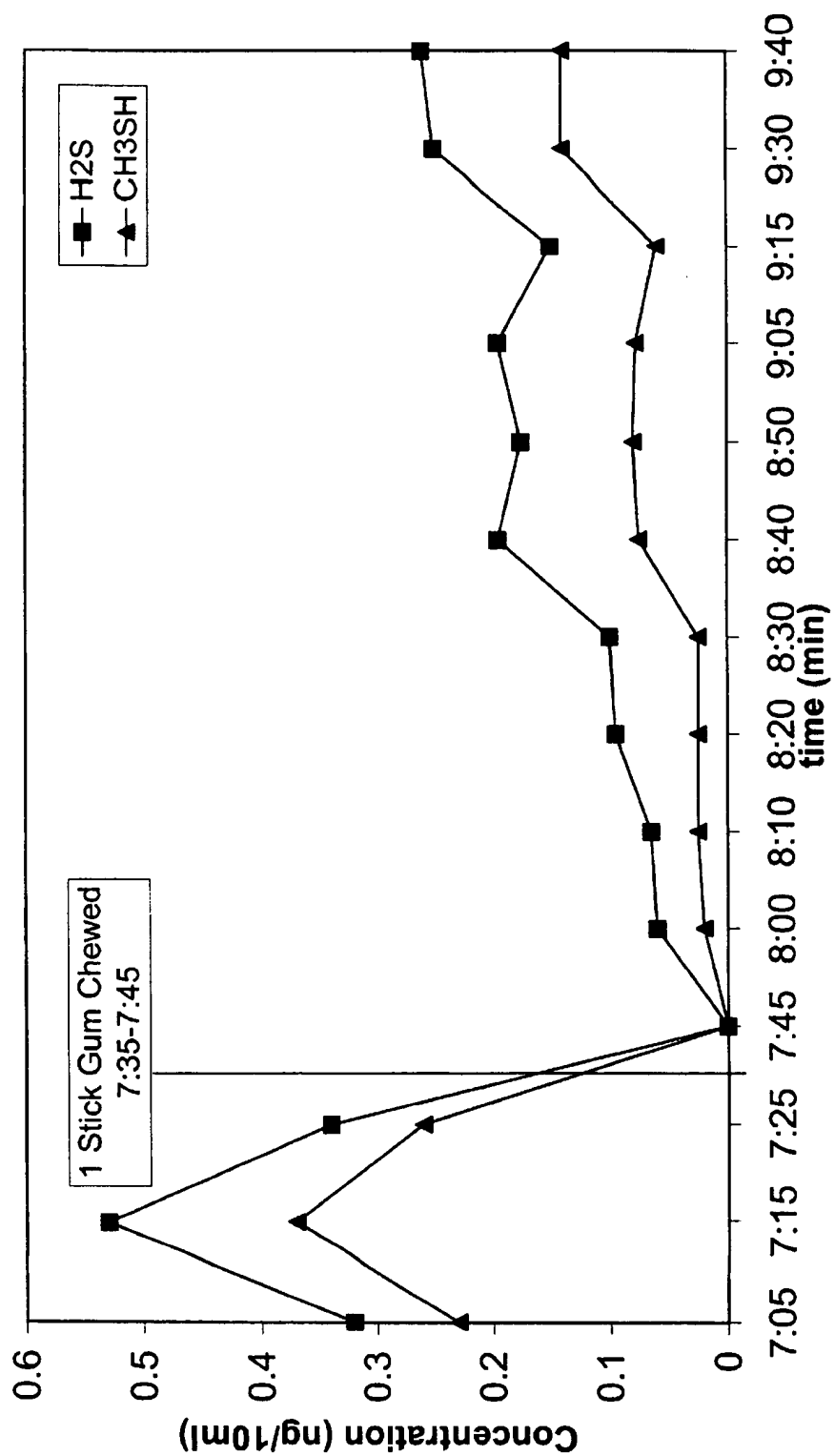
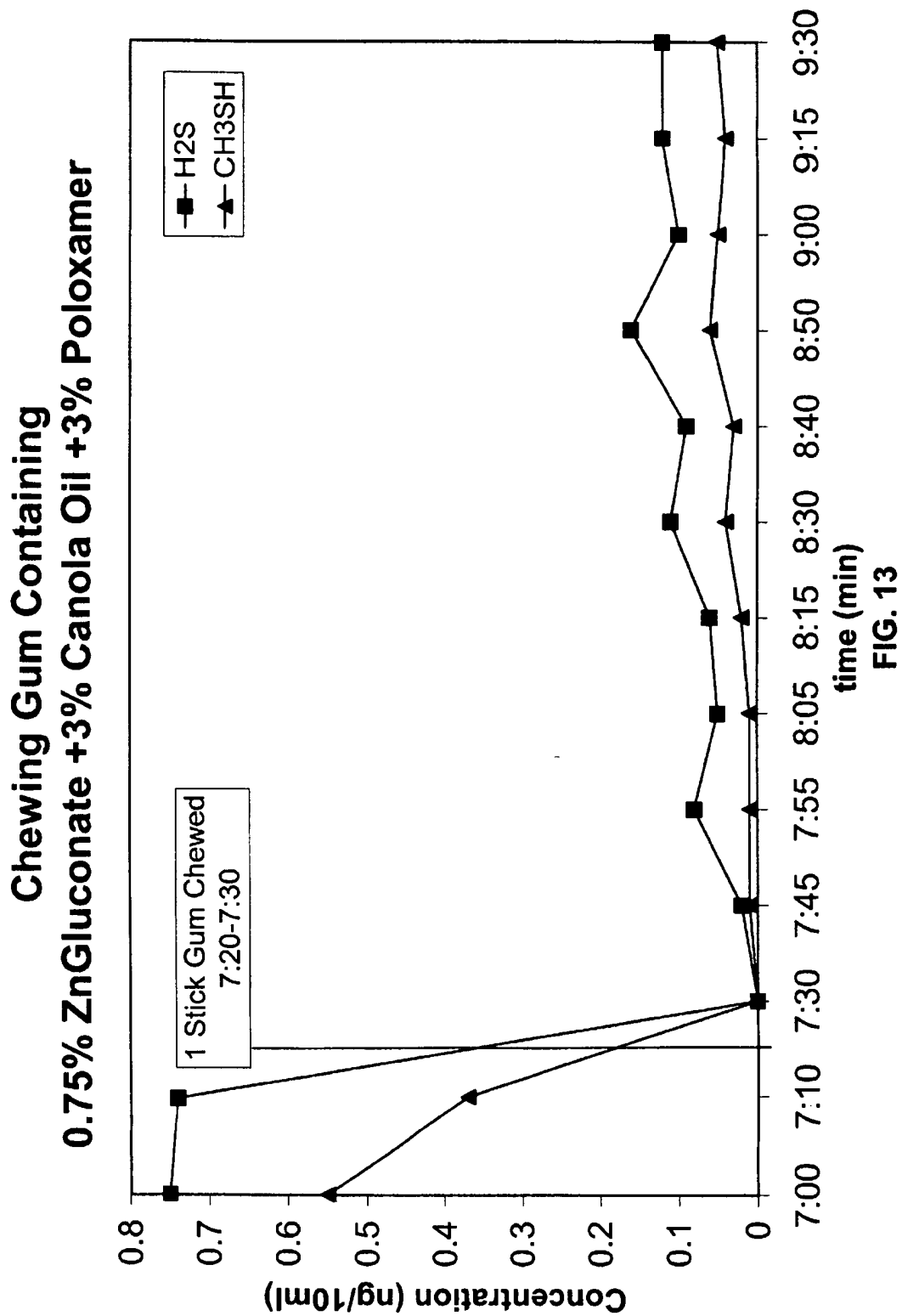


FIG. 12



## Pressed Mint, H2S only

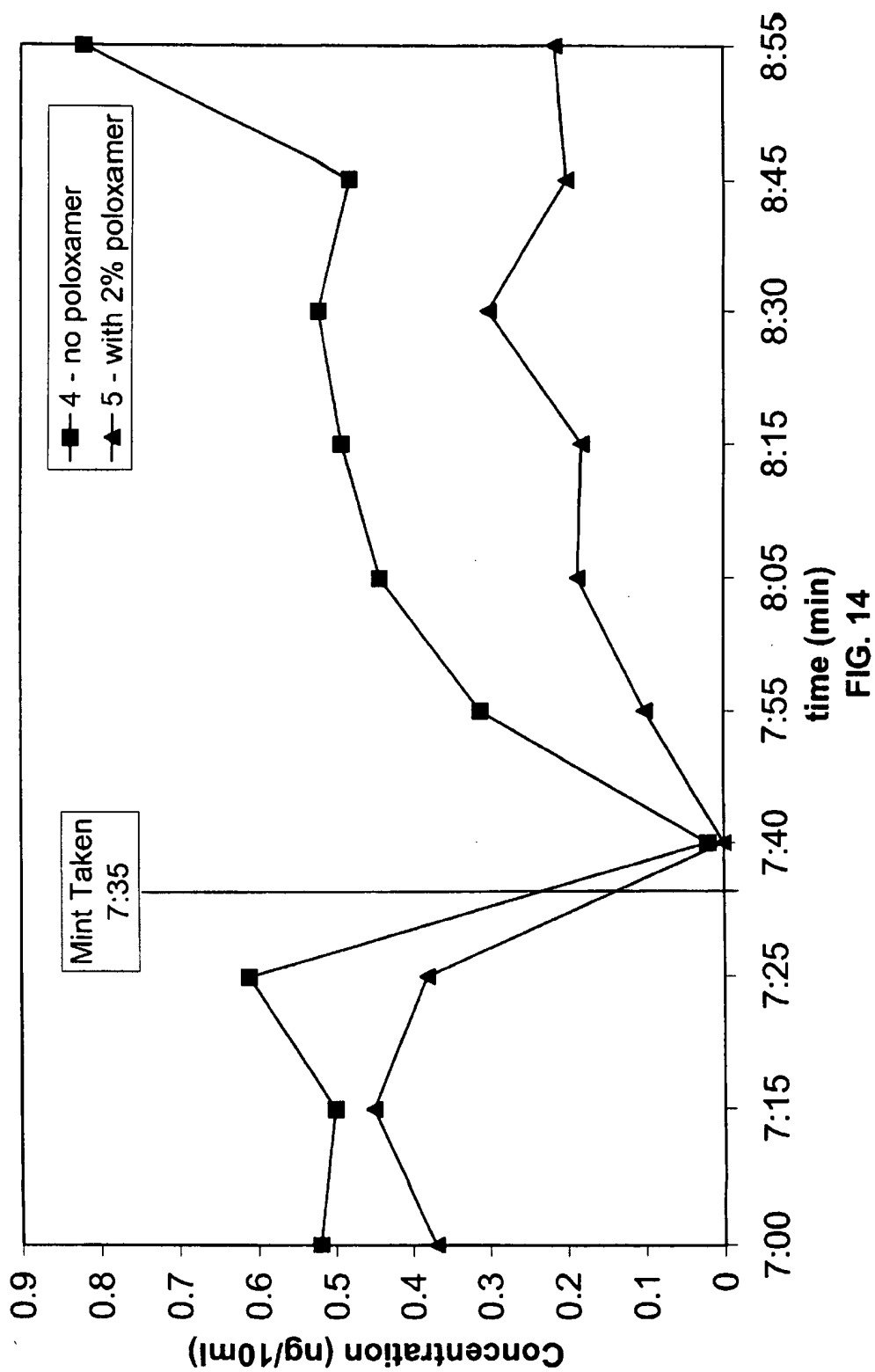
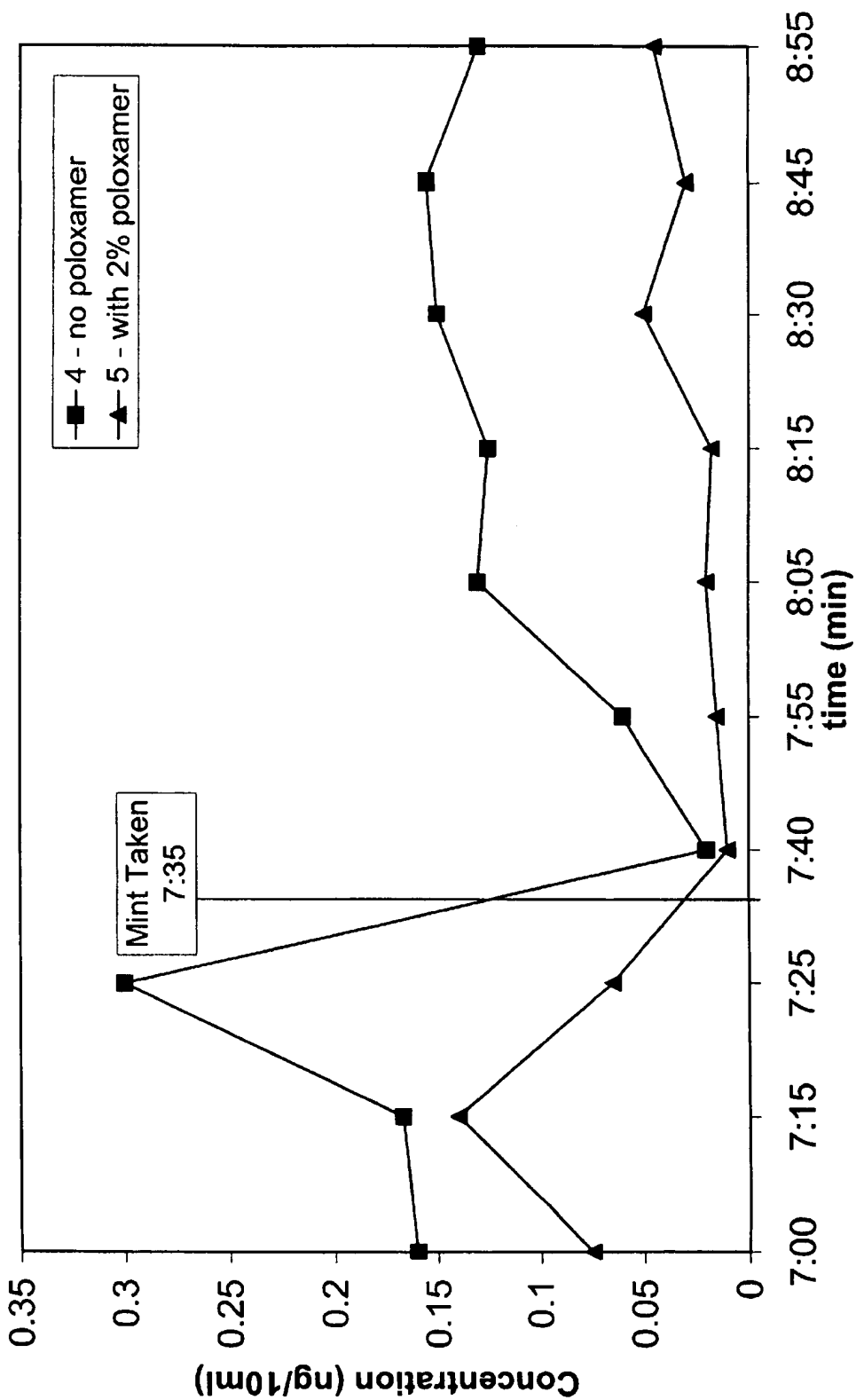
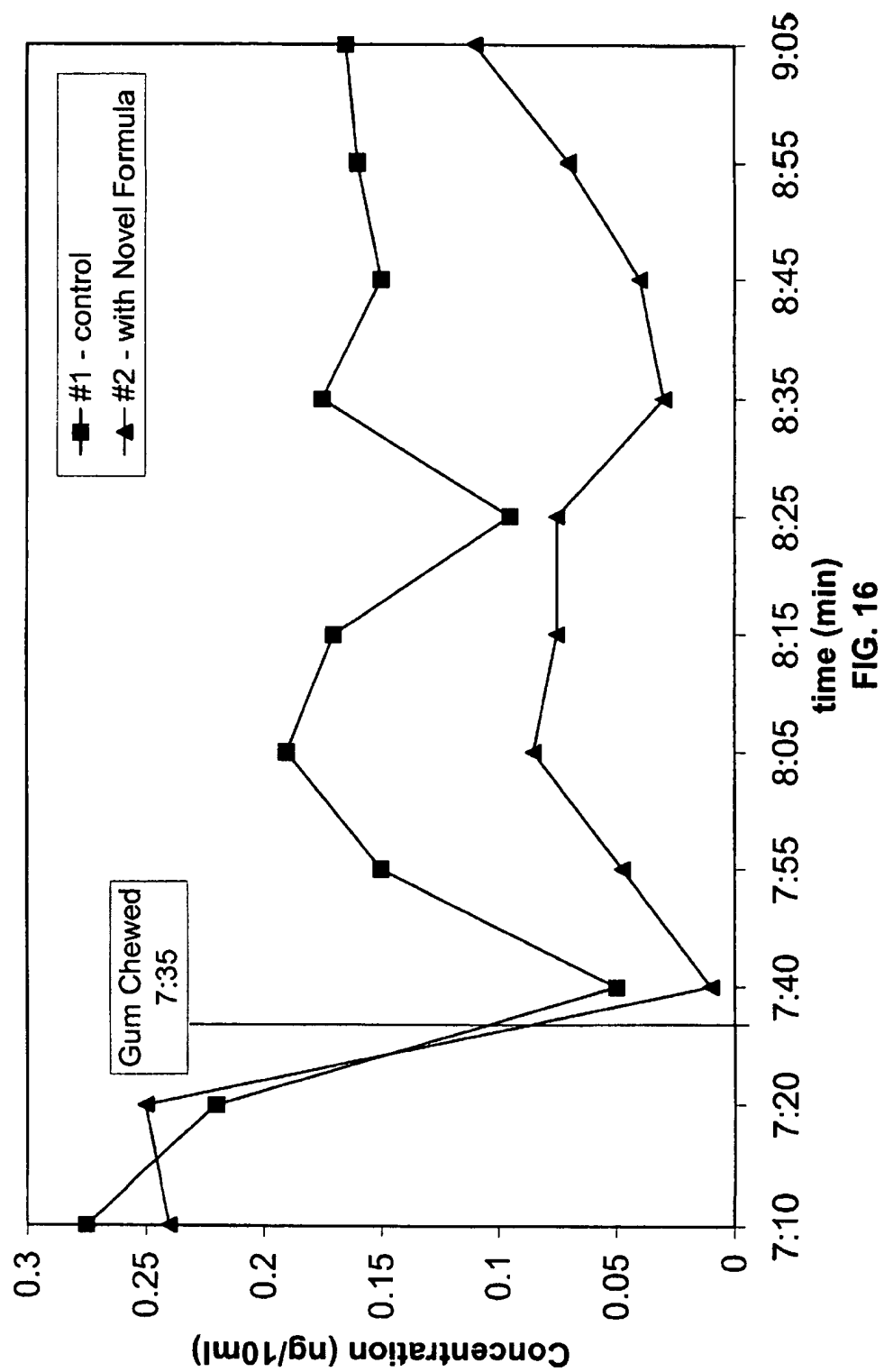


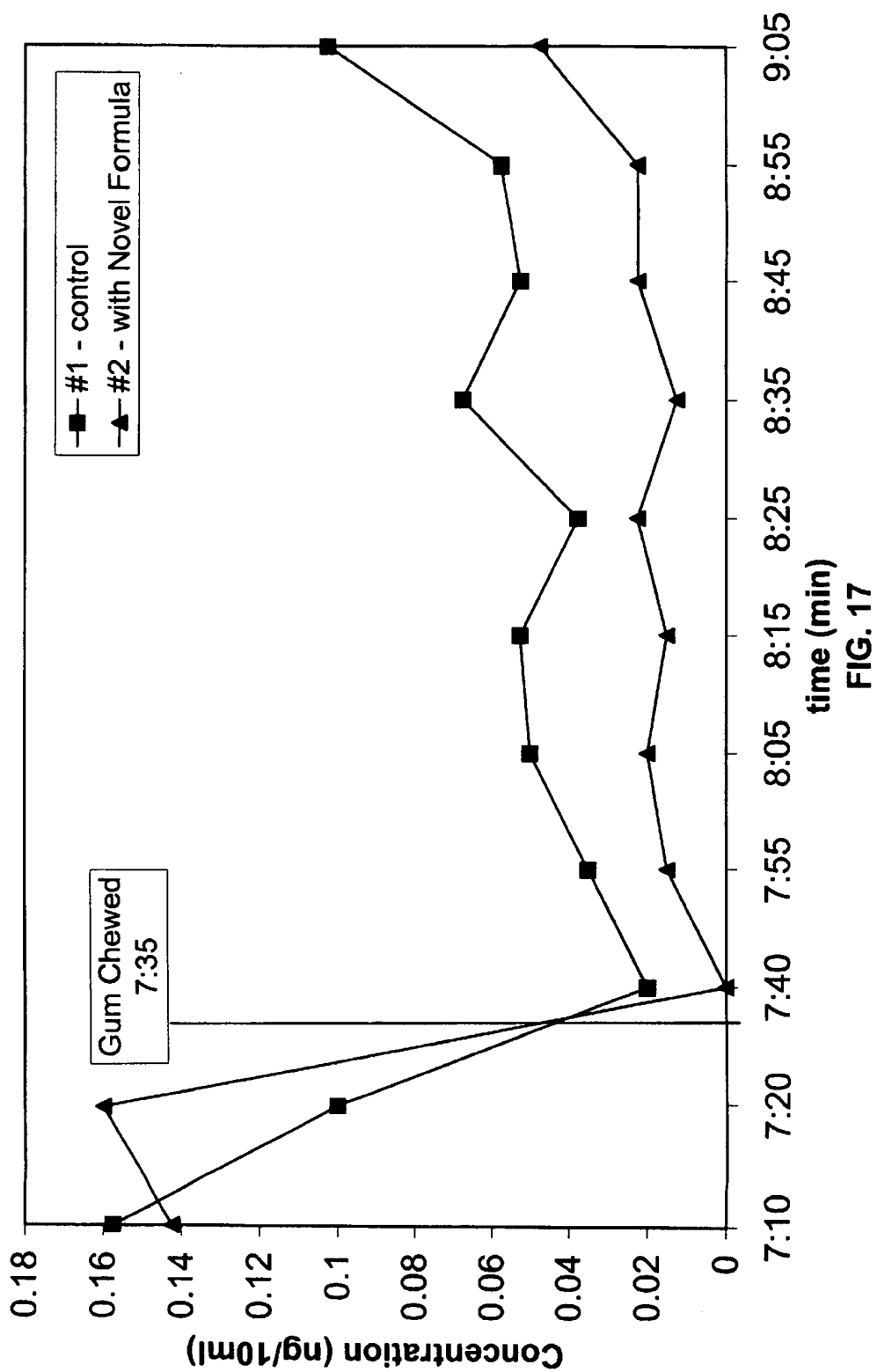
FIG. 14

**Pressed Mint, CH3SH only****FIG. 15**

## Chewing Gum, H2S only



## Chewing Gum, CH3SH only



## BREATH FRESHENING COMPOSITIONS AND METHODS USING THEM

This application is a continuation-in-part of application Ser. No. 08/832,103, filed Apr. 3, 1997, now abandoned.

### BACKGROUND OF THE INVENTION

Volatile sulfur compounds, mainly  $H_2S$  and  $CH_3SH$ , generated in the human oral cavity have been documented to be the primary cause of breath malodor. Generally, the presence of these compounds is most noticeable after long periods of reduced saliva flow and abstinence from food or liquids, resulting in the condition known as "morning breath." Breath malodor can also arise after ingesting various foods such as garlic, cabbage and onions.

Zinc compounds, including zinc salts, have been disclosed in the literature as the active ingredient in mouthwashes, rinses and toothpaste to ameliorate breath malodor.

For example, U.S. Pat. No. 4,814,164, discloses a solid oral formulation comprising a zinc compound, an ionone ketone terpene derivative and preferably a mint flavor as the active ingredient.

A clear aqueous composition useful as a mouthwash comprising a zinc compound complexed to an anionic polymer via a carboxylic moiety is disclosed in U.S. Pat. No. 4,992,259.

Other oral compositions containing zinc compounds including toothpastes, mouthwashes, tablets and lozenges, have been disclosed in U.S. Pat. Nos. 4,138,477, 4,325,939, and 4,469,674.

### SUMMARY OF THE INVENTION

The present invention is directed towards a breath freshening composition which can be used in different confectionery products such as hard candies, pressed mints, tablets, lozenges and chewing gums.

One aspect of the present invention is directed towards the use of a breath freshening composition comprising a physiologically acceptable compound of a divalent metal such as zinc and/or copper, an oil, and a surfactant.

Another aspect of the present invention is directed towards the use of comestible products for humans, such as tablets, lozenges, chewing gums, hard candies, and pressed mints, or comestible products for animals, such as dog biscuits, wherein the comestible products contain a breath freshening composition of the present invention.

The present invention is further directed towards the use of chewing gums, tablets, lozenges, hard and chewy candies and pressed mints which contain a breath freshening composition that has the ability to reduce or eliminate the volatile sulfur compounds which cause bad breath.

One advantageous aspect of the present invention is that in previous products it has often been necessary to employ such a high amount of zinc, to counteract the malodor, that the taste of the zinc became unacceptably pronounced thereby rendering the product unattractive to the consumer. By contrast, the present invention achieves superior breath freshening (malodor control) with lesser amounts of zinc, thereby providing a breath freshening product which does not exhibit an unattractive zinc taste.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1-17 are graphs showing concentration of  $H_2S$  and  $CH_3SH$  versus time in the breath of subjects tested.

## DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to a method of reducing or eliminating  $H_2S$  and  $CH_3SH$  present in the oral cavity, comprising masticating in the oral cavity a comestible product which contains a breath freshening composition comprising a pharmaceutically acceptable compound of a divalent metal, an oil, and a surfactant. Suitable comestible products include tablets, lozenges, chewing gums, hard and chewy candies, pressed mints, and dog biscuits, which contain a breath freshening composition of the present invention.

The term "masticating" includes operations by which an edible product is wholly or partially consumed while it is being held in the mouth, such as by chewing, sucking, or dissolving. Holding the product in the mouth for longer periods of time is associated with greater reduction of  $H_2S$  and  $CH_3SH$  present in the oral cavity, and with more prolonged periods of time before the  $H_2S$  and  $CH_3SH$  return to previous levels in the oral cavity. Suitably effective periods of time range from 3-5 minutes, up to 20-30 minutes.

It has been found that the practice of this method not only reduces or eliminates  $H_2S$  and  $CH_3SH$  present in the oral cavity but also retards the return of those compounds in the oral cavity for a surprisingly prolonged period of time.

The divalent metal compounds of the present invention may include any physiologically acceptable compound effective to ameliorate oral malodor, including the water soluble and sparingly water soluble organic and inorganic salts of such divalent metals.

The preferred divalent metals are zinc and copper. Examples of suitable zinc salts include zinc stearate, zinc acetate, zinc gluconate, zinc lactate, zinc ammonium sulfate, zinc chromate, zinc citrate, zinc dithionate, zinc fluosilicate, zinc tartrate, zinc formate, zinc iodide, zinc nitrate, zinc phenol sulfonate, zinc salicylate, zinc sulfate, zinc succinate, zinc glycerophosphate and the zinc halides, such as zinc chloride. The preferred zinc compounds for use in accordance with the present invention are zinc gluconate and zinc lactate.

Suitable copper salts include the copper analogs of the aforementioned zinc compounds.

The total amount of divalent metal compound(s) present in the breath freshening composition should be 0.5% to 90% by weight, preferably 2% to 70% by weight, of the composition (by weight of the divalent metal(s)).

The oil component of the present invention includes any physiologically acceptable oil, particularly any edible vegetable oil. As used herein, the term "vegetable oil" includes any edible naturally occurring vegetable oil, which as is known are triglycerides of fatty acids in which the acyl portions generally contain 8 to 24 carbon atoms and zero to three carbon-carbon double bonds. The term "vegetable oil" as used herein also includes naturally occurring oils which have been purified and/or modified, for instance by bleaching or by partial or complete hydrogenation. Oils useful in this invention are liquid at ambient temperatures i.e. 40° F.-90° F. One preferred example of an oil is canola oil. Other suitable oils include the low calorie oil based on short and long chain fatty acids which is known by its trade designation "SALATRIM" (Cultor). Other suitable oils include medium chain triglyceride compounds of capric and caprylic acids. An example is Liponate GC from Lipo Chemicals. Suitable oils also include soybean oil and corn oil. Other acceptable oils will be familiar to one of ordinary skill in the art.

The oil component is present in the breath freshening compositions in amounts from 1% to 90% by weight of the composition, preferably 20% to 70% by weight of the composition.

The surfactant component of the breath freshening compositions of the present invention includes a surfactant or a mixture of surfactants. Suitable surfactants include nonionic, anionic, amphoteric and cationic surfactants.

Examples of suitable non-ionic surfactant include:

poly(C<sub>2</sub>-C<sub>4</sub>-alkoxy) esters, and particularly polyoxyethylene ("PEG") esters, of C<sub>8</sub>-C<sub>20</sub> fatty acids, such as polyethyleneglycol oleate and polyethyleneglycol stearate;

C<sub>4</sub>-C<sub>20</sub> alkyl polyglycol ether carboxylates of C<sub>8</sub>-C<sub>20</sub> carboxylic acids including the compounds described in U.S. Pat. No. 4,130,636, which is incorporated herein by reference;

poly(C<sub>2</sub>-C<sub>4</sub>-alkoxy) esters, and particularly polyoxyethylene esters of sorbitan, such as those described in U.S. Pat. Nos. 3,639,563 and 3,947,570, which are incorporated herein by reference;

poly(C<sub>2</sub>-C<sub>4</sub>-alkoxylated) and particularly poly(propoxylated) C<sub>1</sub>-C<sub>20</sub>, alcohols such as cetyl alcohol, including those described in U.S. Pat. No. 2,677,700, which is incorporated herein by reference; and

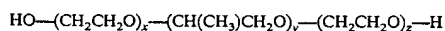
polyethylene glycols, commonly referred to as PEG, and the like.

Other suitable surfactants include block copolymers comprising a congeneric mixture of conjugated polyoxypropylene and polyoxyethylene compounds having as a hydrophobe, a polyoxypropylene polymer of at least 1200 molecular weight, such as those described in U.S. Pat. Nos. 4,343,785, 4,465,663, 4,511,563 and 4,476,107, which are incorporated herein by reference.

These polymers are prepared by adding the required number of moles of propylene oxide to the two hydroxyl groups of propylene glycol to form a hydrophobic base and then adding ethylene oxide to both ends of the hydrophobic base to form hydrophilic polyoxyethylene groups of controlled length. Various species of such polymers, including those defined above as useful in the invention, are available commercially from BASF/Wyandotte Chemicals Corporation of Wyandotte, Mich. under the trademark "Pluronic."

Especially preferred are the commercially available surfactant which include the polyoxyethylene-polyoxypropylene block copolymers such as Pluronic F108 and F127 (BASF) and polysorbates such as Tween 40 and 80 (Hercules).

Most preferred are the non-ionic polyoxypropylene-polyoxyethylene block co-polymers or poloxamers. These polymers have a molecular weight range of 500 to 30,000 and are of the general formula:



wherein x is 2-128, y is 16-67 and z is 2-128.

Suitable anionic, amphoteric and cationic surfactants which are suitable for incorporation into comestible products are well known in this field from published sources and from the knowledge of those skilled in this art.

The surfactant is present in the breath freshening compositions of the present invention from about 1% to 90% by weight, preferably 10% to 70% by weight.

The breath freshening compositions of the present invention are prepared by thoroughly mixing together the divalent cationic component, the oil, and the non-ionic surfactant.

Alternatively, the three components can be added separately, directly to the comestible product in which they are to be provided to the consumer.

Another embodiment of the present invention contemplates the incorporation of the breath freshener compositions of the present invention into chewing gums and solid oral carriers such as slow dissolving tablets or lozenges.

In one aspect of this embodiment, the breath freshening compositions are incorporated into otherwise typical chewing gum compositions manufactured by conventional techniques.

Chewing gums of the present invention comprise the gum base itself, and optionally one or more of solvents, plasticizers, sweeteners, flavorants and/or colorants. Several formulations are possible, depending upon the type of gum desired, i.e., sugar containing or sugarless chewing gums, conventional chewing gums or bubble gums.

The amount of gum base employed will vary greatly depending on various factors such as the type of base used, consistency desired and other components used to make the final product. In general, gum base in amounts of about 5% to about 50% by weight of the final chewing gum composition are acceptable for use in the chewing gum compositions, preferred amounts thereof being about 15% to about 25% by weight.

The gum base may be any water-insoluble gum base known in the art. Illustrative examples of suitable polymers in gum bases include both natural and synthetic elastomers and rubbers. For example, those polymers which are suitable in gum bases include, without limitation, substances of vegetable origin such as natural rubber, chicle, jelutong, gutta percha and crown gum. Further examples of gum bases include rosins, such as comarone resin, pontianak resin, copal gum, kauri gum, dammar gum, sweet bay gum, spruce gum, and balsams.

Conventional chewing gum bases that may be obtained from commercial suppliers are generally suitable.

Additional materials which are also suitable chewing gum base materials include synthetic elastomers such as butadiene-styrene copolymers, isobutylene-isoprene copolymers, polyethylene, polyisobutylene, polyvinyl acetate, and copolymers of vinyl acetate, and mixtures thereof.

The gum base composition may contain elastomer solvents to aid in softening the elastomer component. Such elastomer solvents may comprise methyl, glycerol or pentaerythritol esters of rosins or modified rosins, such as hydrogenated, dimerized or polymerized rosins, or mixtures thereof. Examples of elastomer solvents suitable for use herein include the pentaerythritol ester of partially hydrogenated wood rosin, pentaerythritol ester of wood rosin, glycerol ester of partially dimerized rosin, glycerol ester of polymerized rosin, glycerol ester of tall oil rosin, glycerol ester of wood rosin and partially hydrogenated wood rosin and partially hydrogenated methyl ester of rosin, such as polymers of alpha-pinene or beta-pinene; terpene resins including polyterpene; and mixtures thereof. The solvent may be employed in an amount ranging from about 10% to about 75% and preferably about 45% to about 70% by weight of the gum base.

The gum base can also contain any of a variety of ingredients such as plasticizers or softeners such as lanolin, stearic acid, sodium stearate, potassium stearate, glyceryl triacetate, propylene glycol, glycerol, acetylated monoglyceride, glyceryl diacetate, lecithin, fatty acids, glycerine and the like and/or waxes, for example, natural waxes, petroleum waxes, such as paraffin waxes and microcrystal-

line waxes, to obtain a variety of desirable textures and consistency properties. These individual additional materials are generally employed in amounts of up to about 30% by weight and preferably in amounts of from about 3% to about 20% by weight of the gum base.

The chewing gum composition may additionally include conventional additives such as emulsifiers such as lecithin and glyceryl monostearate; and additional fillers such as dicalcium phosphate, tricalcium phosphate, aluminum hydroxide, magnesium hydroxide, alumina, aluminum silicates, calcium carbonate, and talc and combinations thereof. These fillers may be used in the gum base in various amounts. Preferably the amount of fillers when used will vary from about 4 to about 30% by weight of the chewing gum.

Another aspect of this embodiment contemplates the incorporation of a breath freshening composition into a solid carrier such as a tablet or lozenge.

The solid carrier is sugar or a water soluble polyhydric alcohol (polyol) such as mannitol, xylitol, sorbitol, maltitol, a hydrogenated starch hydrolysate ("Lycasin"), hydrogenated glucose, hydrogenated disaccharides, and/or hydrogenated polysaccharides, as the major ingredient, in an amount of about 85-98% by weight of the total carrier. Solid salts such as sodium bicarbonate, sodium chloride, potassium bicarbonate or potassium chloride may totally or partially replace the polyol carrier.

Tableting lubricants, in minor amounts of about 0.1 to 5% by weight, may be incorporated into the tablet or lozenge formulation to facilitate the preparation of both the tablets and the lozenges. Suitable lubricants include vegetable oil such as coconut oil, magnesium stearate, aluminum stearate, talc, starch and Carbowax.

Lozenge formulations contain about 2% hydrocolloid as a barrier agent to provide a shiny surface as opposed to a tablet which has a smooth finish.

The lozenge or tablet may optionally be coated with a coating material such as waxes, shellacs, carboxymethyl cellulose, polyethylene/maleic anhydride copolymer or Kappa-carrageenan, to further increase the time it takes the tablet or lozenge to dissolve in the mouth. The coated tablet or lozenge is slow dissolving, providing a sustained release rate of the active ingredients of about 3 to 5 minutes.

The breath freshening compositions of the present invention are incorporated into a lozenge or tablet by conventional mixing and tableting techniques known in this field.

The present embodiment further contemplates the optional inclusion of a sweetener, flavorant, or colorant component into the chewing gums, tablets or lozenges containing the breath freshening composition.

The sweetener component comprises any one or more sweeteners known in the art, including both natural and artificial sweeteners. The sweetener may be chosen from a wide range of materials, including water-soluble sweeteners, water-soluble artificial sweeteners and dipeptide based sweeteners and mixtures thereof. Thus, sweeteners may be chosen from the following non-limiting list, which includes sugars such as sucrose, glucose, corn syrup, dextrose, invert sugar, fructose and mixtures thereof; saccharine and its various salts such as the sodium or calcium salt; cyclamic acid and its various salts such as the sodium salt; free aspartame; dihydrochalcone sweetening compounds; glycyrrhizin; Stevia rebaudiana (Stevioside); monellin, thaumatin, Sucralose, isomaltitol, neosugar, lactitol, polydextrose, tagatose, and maltitol; and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol, chalcone and the like. Also contemplated as a sweetener is the nonfer-

mentable sugar substitute hydrogenated starch hydrolysate (also known as Lycasin) which is described in U.S. Pat. No. Re. 26,959. Also contemplated is the synthetic sweetener 3,6-dihydro-6-methyl-1,2,3-oxathiazin-4-one-2,2-dioxide, particularly the potassium (Acesulfame-K), sodium and calcium salts thereof as described in German Patent No. 2,001,017.7. Sorbitol is the preferred sweetening and bulking agent.

The amount of sweetener included is an amount effective to provide the desired degree of sweetness and bulk, generally 0.001 to 70 wt. % of the chewing gum, tablet or lozenge.

Suitable flavorants include both natural and artificial flavors and mints, such as oil of peppermint, menthol, oil of spearmint, vanilla, oil of cinnamon, oil of wintergreen (methyl salicylate), and various fruit flavors, including but not limited to lemon oil, orange oil, grape flavor, lime oil, grapefruit oil, apple, apricot essence, and combinations thereof. The flavorings are generally utilized in amounts that will vary depending upon the individual flavor, and may, for example, range in amounts of about 0.5% to about 3% by weight of the chewing gum, tablet or lozenge.

Colorants can be present in the chewing gums, tablets or lozenges of the present invention. Examples include pigments such as titanium dioxide, natural food colorants such as beta carotenes, betanin, turmeric, and other dyes suitable for food, drug and cosmetic applications known as F.D. & C. dyes, and the like. The materials may be incorporated in amounts of up to about 1% by weight, preferably up to about 6% by weight of the chewing gum, tablet or lozenge.

When the breath freshening compositions of the present invention are incorporated into hard candies, pressed mints, lozenges or tablets, the divalent metal compound is present in an amount from about 0.1 to 0.75% by weight, the oil in an amount from about 0.1 to 3% by weight, and the surfactant in an amount from about 0.1 to 3% by weight.

A representative formulation for a hard candy embodying the composition of the present invention is as follows:

Sorbitol	94-98 wt. %
Magnesium Stearate	0.6-0.8
Colorants	1.5-4.
Flavor	<1.
Sweetener	0.1-0.2
Breath freshening composition of the present invention	0.1-4.0

The present invention will be further illustrated with reference to the following examples which will aid in the understanding of the present invention, but which are not to be construed as limitations thereof.

The instrumentation and test procedures employed in the examples which appear below and in obtaining the data reported herein, were as follows:

#### GAS CHROMATOGRAPH SET-UP AND CALIBRATION

A Hewlett Packard 5890 gas chromatograph was modified for the breath sampling work. The injector was equipped with a 10 port Valco sampling valve ordered from Supelco Inc. Bellefonte, Pa. (cat#2-2981M) and a 16.5'x1/8" O.D. Teflon sample loop. With a 1/16" I.D., this tube has a volume of 10 milliliters. The valve configuration with attached tubes are shown in FIGS. 1A and 1B. The chromatographic column was 25'x1/8" Teflon packed with 5% polyphenol ether (5 ring) and 0.5% phosphoric acid on 40/60 mesh

Teflon (Supelco). Condition column at 120° C. overnight. All the tubing, valves and connections in contact with the sulfur compounds were Teflon coated, since glass or metal tend to absorb these compounds making consistent, reliable results difficult to obtain.

The gas chromatograph utilizes a Flame Photometric detector (FPD). Dry compressed air was used as the carrier gas to eliminate the solvent front peak from the chromatogram. Carrier gas flow was 13.3 mls/min, however, since the flowmeter on this GC is calibrated for nitrogen, the flow was set to a 20. mls/min reading to compensate.

The oven temperature profile is 70–100° C. @ 6 degrees/min. 1 min at 70 and 1 min at 100° C. The injector temperature is 100° C. and the detector temperature is 150° C. The total run time is 7.0 minutes with H<sub>2</sub>S eluting at 2.1 minutes and CH<sub>3</sub>SH eluting at 2.8 minutes. At this rate a sample can be taken every 10–15 minutes. A third peak may appear at times, identified as dimethyl sulfide (CH<sub>3</sub>—S—CH<sub>3</sub>), which is not a primary peak of interest and usually represents less than 1% of the total area.

Calibration of the instrument was accomplished using standard gas permeation tubes ordered from VICI Metronics (Santa Clara, Calif.). The tubes which emitted the sulfur compounds at a constant rate (H<sub>2</sub>S=100 ng/min and CH<sub>3</sub>SH=65 ng/min), were placed inside a Teflon cylinder (in a 30° C. water bath) and connected to a dry-air source. The concentrations vary with each new set of standards. A soap film flowmeter measured flow and thru calculation the concentration being injected into the GC was determined. The calibration procedure is a multi-level external standard using peak area response.

#### GAS CONCENTRATION CALCULATION

Permeation tube gas rates: H<sub>2</sub>S = 105 ng/min  
CH<sub>3</sub>SH = 55.1 ng/min.

Calculation:  $\frac{(\text{gas rate}) \text{ ng/min}}{(\text{air flow}) \text{ ml/min}} = \frac{\text{ng}}{\text{ml}} \text{ of gas}$

#### BREATH SAMPLING TECHNIQUE

1. Subject is asked not to eat or drink for a period of 12 hours before testing.
2. The morning of the test the subject was to refrain from normal morning oral hygiene (i.e. brushing teeth, using mouthwash, etc.), eating or drinking.
3. For each sample the subject was asked to hold their mouth closed while breathing through the nose, to allow equilibration of mouth air for one minute, and not swallow.
4. After one minute, subject inserted the Teflon sample tube through their tightly closed lips into the mouth to a depth of 2.25 inches. The shoulder of the mouthpiece marked the limit of insertion. The end of the tube was placed toward the back of the mouth over the center of the tongue.
5. During sample withdrawal (about 5 seconds), the subject was asked to stop breathing. A thirty milliliter sample of mouth air was drawn to fill the 10 ml GC sample loop using a 60 ml disposable syringe.
6. The sample tube was removed from the mouth, and the sample was injected into the GC using the switching valve and the run started. Samples were generally taken every 10–15 minutes until the completion of the test. The average test time is 2 hours 30 minutes.

In the following examples, the data readings of the H<sub>2</sub>S and CH<sub>3</sub>SH content of the subject's breath before the comestible product was taken into the mouth provided a baseline corresponding to the untreated levels of those components. Readings of H<sub>2</sub>S and CH<sub>3</sub>SH of the subject's breath, taken at intervals of time after the comestible product had been taken, provided a means for monitoring the length of time that elapsed until the H<sub>2</sub>S and CH<sub>3</sub>SH levels returned to the baseline levels. A longer elapsed time to return to baseline corresponds to greater suppression of malodor.

The data reported in the following examples show that comestible products (here, a pressed mint product and an otherwise conventional chewing gum) containing the combination of zinc salt, edible oil, and nonionic surfactant in accordance with the present invention provide substantial suppression of H<sub>2</sub>S and CH<sub>3</sub>SH in the oral cavity for prolonged periods of time.

This suppression always significantly exceeded that obtained with a pressed mint control product of identical composition except that the combination of zinc salt, edible oil and nonionic surfactant was not present. The performance of the control pressed mint product is shown in FIG. 1. The vertical line marked with an "x" represents the time at which the product was taken into the mouth. As can be seen, by only 20 minutes later the levels of H<sub>2</sub>S and CH<sub>3</sub>SH in the oral cavity had returned to the levels they had at the time that the product was initially taken into the mouth.

FIGS. 2 through 9 show the performance of the same pressed mint containing a zinc salt, an edible oil, and a nonionic surfactant, in varying amounts of those three components. As with FIG. 1, the vertical line marked with an "X" denotes the time at which the subject took the product into the mouth. The data show that products containing 0.25% zinc salt or containing 0.5% zinc salt had malodor suppressing effect which extended far longer than the control was able to provide. These results are summarized in Table 1.

FIGS. 10 through 13 exhibit readings taken with a conventional chewing gum, both without the breath freshening composition of the present invention (seen as the control line in FIG. 10 and with the breath freshening composition of the present (FIGS. 11 through 13) invention, in varying amounts of the zinc salt, edible oil and nonionic surfactant. These results are summarized in Table II.

Again, it can be seen that comestibles containing the breath freshening composition of the present invention exhibit substantial, significant control of the H<sub>2</sub>S and CH<sub>3</sub>SH associated with malodor of the breath. Indeed, the H<sub>2</sub>S and CH<sub>3</sub>SH remained below the previous baseline levels for well over 2 hours, and essentially indefinitely, without showing an indication of returning to the baseline levels.

FIGS. 14 and 17 show the breath freshening (malodor control) effectiveness of comestible (pressed mints and gum) products with and without the nonionic surfactant. It can be seen that the surfactant significantly contributes to the malodor control provided by this invention. Thus, it is clear that the present invention represents not merely another zinc-based breath freshening product but a synergistic composition which provides improvement to an unexpected extent not previously attainable.



UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,030,605  
DATED : February 29, 2000  
INVENTOR(S) : Ronald P. D'Amelia

Page 1 of 1

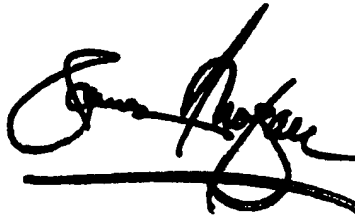
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,

Item [75], "Ronald P. D'Ameila" should read -- Ronald P. D'Amelia --

Signed and Sealed this

Twenty-fourth Day of June, 2003

A handwritten signature in black ink, appearing to read "James E. Rogan", with a long horizontal flourish extending from the bottom of the signature.

JAMES E. ROGAN  
*Director of the United States Patent and Trademark Office*

**SUMMARY APPENDIX**

<b>Claim 1</b>	<b>Drawings</b>	<b>Specification</b>
<p>A chewing gum comprising:</p> <p>        a coated gum center, wherein the gum center and coating both include a metal salt that is designed to provide breath freshening characteristics to a consumer of the chewing gum.</p>		<p>Page 3, lines 28-29; Page 5, lines 16-19.</p>

<b>Claim 12</b>	<b>Drawings</b>	<b>Specification</b>
<p>A chewing gum product comprising:</p> <p>        a metal salt that is designed to provide breath freshening characteristics;</p>		<p>Page 2, lines 20-22; Page 5, lines 16-19.</p>
<p>        a gum center including a water-soluble portion, a water-insoluble portion, wherein the gum center includes the metal salt; and</p>		<p>Page 2, lines 23-24; Page 3, lines 24-26; Page 3, lines 28-29; Page 4, lines 6-7; Page 4, lines 10-13; Page 5, lines 16-19.</p>
<p>        a coating surrounding the gum center, including a cooling agent and a metal salt.</p>		<p>Page 2, lines 24-25; Page 3, lines 26-29; Page 5, lines 16-19; Page 8, lines 11-12.</p>

<b>Claim 28</b>	<b>Drawings</b>	<b>Specification</b>
A product containing a metal salt designed to provide breath freshening properties, comprising:		Page 2, lines 20-22; Page 5, lines 16-19.
a gum center including a metal salt selected from the group consisting of zinc and copper salts, a water-soluble portion, a water-insoluble portion; and		Page 3, lines 28-29; Page 5, lines 16-21.
a coating surrounding the gum center, including a cooling agent and a metal salt selected from the group consisting of zinc and copper salts.		Page 2, lines 24-26; Page 3, lines 28-29; Page 5, lines 16-19; Page 6, lines 5-7; Page 8, lines 11-12.

<b>Claim 34</b>	<b>Drawings</b>	<b>Specification</b>
A method for treating halitosis comprising the steps of  chewing a chewing gum comprising a coated gum center including a water-soluble portion, a water-insoluble portion, wherein the coating at least substantially surrounds the gum center, the coating and gum center being prepared with a metal salt ingredient designed to provide breath freshening characteristics, the combined amount being a therapeutically effective amount.		Page 2, lines 20-26; Page 3, lines 28-29; Page 4, lines 14-16; Page 5, lines 16-20.

Claim 40	Drawings	Specification
<p>A chewing gum product comprising:</p> <p>        a gum center including a water-soluble portion and a water-insoluble portion; and</p>		<p>Page 2, lines 23-25;  Page 3, lines 25-26;  Page 4, lines 6-7;  Page 4, lines 11-12;  Page 8, lines 25-28;  Page 10, lines 24-25.</p>
<p>        a coating including a copper salt.</p>		<p>Page 3, lines 28-29;  Page 5, lines 16-19.</p>